



Contour. next **USB**

Blood Glucose
Monitoring System



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

USER GUIDE

INTENDED USE

Bayer's CONTOUR[®]NEXT USB blood glucose monitoring system (meter, test strips and control solution) is intended for use by persons with diabetes for self-testing, and by health care professionals for use on a single patient. The CONTOUR NEXT USB system is intended for the quantitative measurement of glucose (from 1.1 mmol/L to 33.3 mmol/L) in fresh capillary whole blood samples drawn from the fingertip or palm. Venous whole blood samples may also be used by health care professionals.

The CONTOUR NEXT USB blood glucose monitoring system may be used as an aid to monitor the effectiveness of an individual's personal blood glucose control program. The system is not intended for the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates.

INFORMATION FOR SAFETY



WARNINGS

Serious illness


- Capillary (fingertick 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.^{1,2}

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 2.8 mmol/L; follow medical advice immediately.

- If your blood sugar reading is over 13.9 mmol/L, 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 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
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- The MICROLET[®]2 lancing device is not suitable for use by health care professionals. 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.
- 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.

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 Bayer Diabetes Care Customer Service 9 a.m. to 9 p.m. EST, seven days a week, at 1-800-268-7200 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 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven 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 5°C and 45°C. 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 5°C and 45°C.

- 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 TÜV.
- 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 mmol/L (millimoles of glucose per liter of blood).
 - Results in mmol/L will **always** have a decimal point;
 - Results in mg/dL will **never** have a decimal point.

Example: 5.2^{mmol/L} or 93^{mg/dL}

- Check your display screen to be sure the results are shown the right way. If not, contact Bayer Diabetes Care Customer Service 9 a.m. to 9 p.m. EST, seven days a week, at 1-800-268-7200.
- Bayer's CONTOUR NEXT USB blood glucose monitoring system has a measuring range of 1.1 mmol/L to 33.3 mmol/L.
 - For results over 33.3 mmol/L or under 1.1 mmol/L:
 - If your blood sugar reading is under 1.1 mmol/L, 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 33.3 mmol/L, 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.
- Please be aware that USB ports in some computers and self-powered 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.

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 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.

You must unplug your CONTOUR NEXT USB meter to test.

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Bayer's CONTOUR[®]NEXT USB Blood Glucose Monitoring System

Protective USB Cap

Top Menu Button

See page 4

Selection/Scrolling
Buttons

See page 5

Display Screen

Test Strip Port

To turn on the test strip port
light, see page 4.

Your CONTOUR[®]NEXT Test Strip

Grey Square End

Insert this end into the test strip port with
the grey 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

Re-setting Handle

Grip Indent

Release Button

Lancet Holder

Lancet

Round Protective Cap

Endcap Dial

Adjustable Endcap
(fingertip)

Alternative Site Testing
Clear Endcap* (May not
be included in all kits)
(palm)

*Available on request from Bayer Diabetes Care Customer Service,
call 1-800-268-7200.

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:

- 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 ▲ or ▼ 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".

Initial Setup



Before use, charge your meter. See page 68.

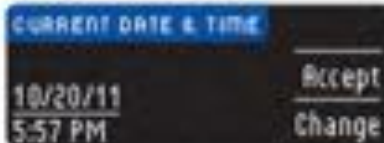
HINT: Your meter comes with GLUCOFACTS® DELUXE diabetes management software on board. You do not need to set this up to charge your meter or perform a blood sugar test. Please see page 63 for more information on GLUCOFACTS DELUXE.

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 **▲** or **▼** button to select your desired language. Press the **▼** button to scroll down to see more language choices.

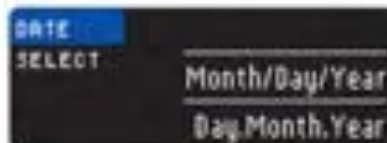
When your language is highlighted, press the **OK** button. A screen confirms your language.



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 **▲** or **▼** 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.



Highlight your choice and press **OK**.

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



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

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.



WARNING

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

Your meter comes preset with a High Alert level of 13.9 mmol/L and a Low Alert level of 3.9 mmol/L. 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**.



HINT: Your Target Ranges must be within your High and Low Alert levels. You will set your target ranges next.

2. If you selected **Change**, press the **▲** or **▼** button to select your High Alert level. This can be set between 7.0 - 20.0 mmol/L. Press **OK**.



3. Press the **▲** or **▼** button to select your Low Alert level. This can be set between 3.0 - 6.7 mmol/L. Press **OK**.



HINT: Pressing and holding the **▲** or **▼** buttons will scroll through the numbers more quickly.

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



Target Ranges

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

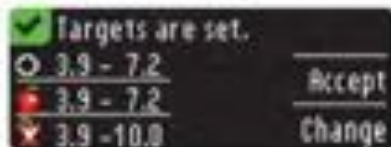
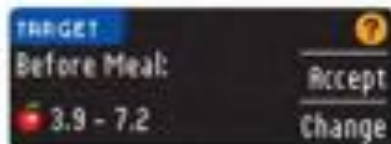


Discuss your Target ranges with your health care professional.

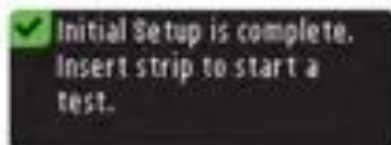
You can accept or change these ranges.

Each Target will have an option to Accept or Change.

- To change the Targets press the ▲ or ▼ buttons until the desired Target is reached and then press OK. The preset value for Fasting and Before Meal is 3.9 - 7.2 mmol/L and for After Meal is 3.9 - 10.0 mmol/L.



A screen confirms your choice for each Target.



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

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 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven 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 MICROLET 2 lancing device and MICROLET[®] lancets. You may also need CONTOUR NEXT control solution to perform a quality control check.

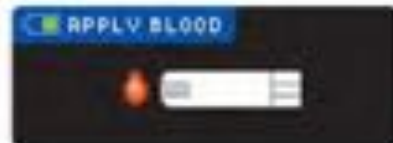


Always wash and dry your hands well with soap and water before and after testing, handling the meter, lancing device or used test strips.

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



- Hold the test strip with the grey end facing toward the meter.
- Insert the grey 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.

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.



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 MICROLET 2 lancing device is intended for single patient use only. The MICROLET 2 device should not be used for assisted blood draws by health care providers or at health care provision sites, and should never be shared with anyone else, even a family member due to risk of infection.

Use a new MICROLET® 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.



2. Loosen the round protective cap on a lancet by rotating it $\frac{1}{4}$ 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.



5. Replace the grey endcap.



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

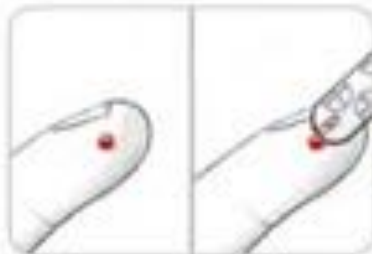
Getting the Blood Drop for Fingertip Testing



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



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

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

Do not press the tip against the skin or place the blood on top of the test strip or you could get inaccurate results or errors.

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 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.



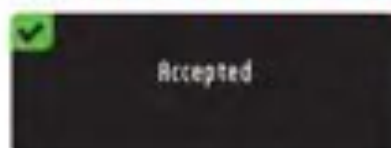
Your test result appears as a large-sized number and then changes to the usual test result screen.



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.

For Alternative Site Testing (AST) - Palm

**WARNING**

Ask your health care professional if Alternative Site Testing is right for you.

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 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven days a week).

Getting a Blood Drop for Alternative Site Testing



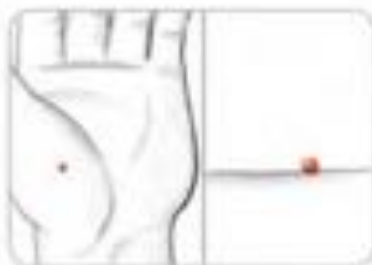
1. Wash your hands and the puncture site with soap and warm water. Rinse and dry well.
2. Attach the clear AST endcap to the MICROLET[®]2 lancing device.



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.



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



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

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

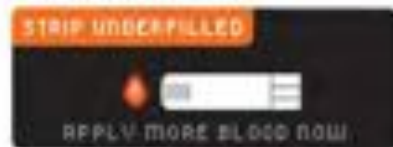
Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.

Do not test the blood sample from palm if you get:

- Smearred blood
- Clotted blood
- Runny blood
- Clear fluid mixed with the blood.

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.

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 3.9 mmol/L or above 13.9 mmol/L, 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

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



WARNING: Potential Biohazard

- The 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! 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 3.9 - 6.1 mmol/L in the fasting state.⁵



WARNING

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

Cleaning and Disinfection

Your CONTOUR[®]NEXT USB system should be cleaned and disinfected once a week. Use **only** 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.

WARNING

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

NOTE: If your meter is being operated by a second person who is providing testing assistance, the meter and lancing device should be disinfected prior to use by the second person. Health care professionals should follow their institution's policy on the frequency of disinfection.

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 MICROLET 2 lancing device have been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). These devices have been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should call Bayer Diabetes Care Customer Service for assistance if your device malfunctions for any cause or if you notice any changes in the meter case or display.

For more information see:

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

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

Health Canada Advisory : Blood Lancing Devices for Personal Use May Transmit Blood-Borne Viruses if Used On More Than One Person (2009)

http://www.hc-sc.gc.ca/aahc-asc/media/advisories-avis/_2009/2009_50-eng.php

Cleaning Your Meter

Supplies Needed for Cleaning:

- Germicidal wipes containing 0.55% sodium hypochlorite (bleach) • Paper towels
1. Carefully clean the meter with 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:

- 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 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.*

Disinfecting Your Meter



Buttons

USB Connector
(under cap)

Strip Port

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

Cleaning Your Lancing Device

Supplies Needed for Cleaning:

- Germicidal wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels

1. Clean the MICROLET[®]2 lancing device with germicidal wipes until all soil is removed.
2. Dry as necessary with a clean paper towel.

Disinfecting Your Lancing Device

Supplies Needed for Disinfecting:

- 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 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 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 MICROLET 2 lancing device has been demonstrated to withstand 5 years of cleaning and disinfection without damage. However, if your device malfunctions for any cause, contact Bayer Diabetes Care Customer Service at 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, 7 days a week) to troubleshoot the issue and provide a solution.

Warranty

Your MICROLET 2 lancing device is warranted for 5 years.

High and Low Blood Sugar Alert Screens

Your meter has been preset with a low blood sugar (hypoglycemia) value of 3.9 mmol/L and a high blood sugar (hyperglycemia) value of 13.9 mmol/L. These are the preset values, but can be customised by you and/or your health care professional.

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



- A screen with large-sized 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 large-sized 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.



WARNING

- 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, 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.

Control Solution Testing

Use only Bayer's CONTOUR[®]NEXT control solutions with your 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.

Normal, Low or High control solutions are available. If you need help locating Bayer's CONTOUR[®]NEXT control solutions, call Bayer Diabetes Care Customer Service at 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven days a week).

1. Remove the test strip from the bottle and firmly snap the lid closed.
2. Hold the test strip with the grey 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 non-absorbent 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.

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 Bayer Diabetes Care Customer Service at 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven days a week). Do not use the meter or test strips for blood glucose testing until you resolve this issue.

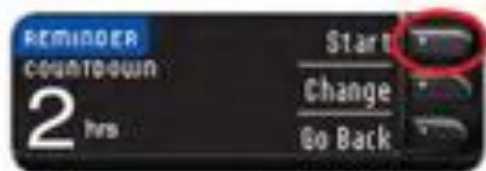
Setting a Test Reminder After Testing

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.

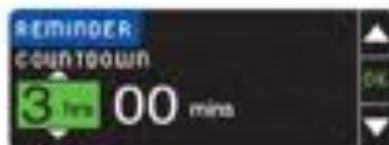
1. With the test strip still in the meter, press the **Reminder** button.



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 **OK** button.



4. Press the **▲** or **▼** button to select the minutes (in 15 minute increments). Press the **OK** 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.

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 is:" with the remaining amount of time displayed.

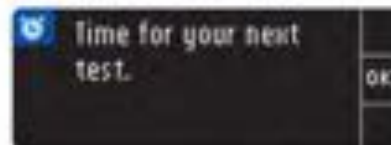
2. To stop the Countdown, press the **Stop** button.



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 **OK** button, insert a test strip and proceed with testing. 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.

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.

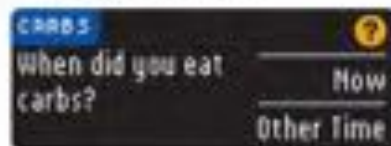


If you are using this option for the first time, you will need to select one of the carb units of measurement: Grams, Points, or Choices. Ask your health care professional whether you should be tracking your carbs in grams, points, or choices.



A screen will confirm your selection.

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**.

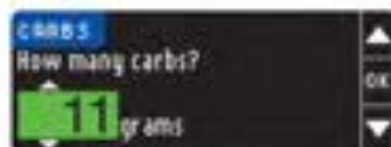
If you would like to enter carbs for a different time, choose **Other Time**.

Select **Today** or **Yesterday**.



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

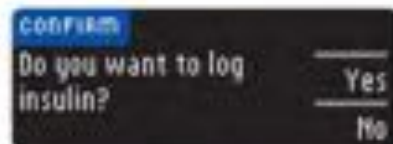
4. Enter the amount of carbs in the meal.



Press the **▲** or **▼** 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.



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.

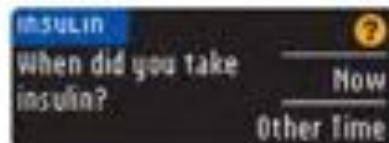
Log Insulin Information after Testing



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.



If you are taking insulin now, select **Now**.

If you would like to enter insulin 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 **OK** after each selection.

3. Select your insulin type.



4. Enter the amount of insulin in units using the ▲ or ▼ button.



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.
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 ▲ or ▼ button to scroll faster.

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 Options button.



2. Press Notes.

3. Press the ▲ or ▼ 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.

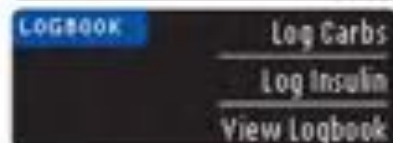
After the confirmation screen disappears, you may remove the note or add additional Notes by repeating the steps above. The Notes will scroll across the bottom so that you can read them all.

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.



3. Select **Logbook**.



4. Select **Log Carbs**.

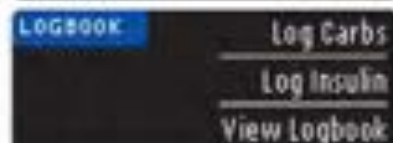
5. Then follow steps 2 to 5 in the previous instructions to log carbs information.

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.



3. Select **Logbook**.



4. Select **Log Insulin**.

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

Reviewing the Logbook

The Logbook menu contains **Log Carbs**, **Log Insulin** and **View Logbook**.

To review entries in the Logbook:

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

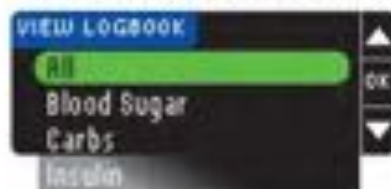


2. Select **Logbook**.



3. Select **View Logbook**.

4. You can select **All**, **Blood Sugar**, **Carbs** or scroll down using the **Down Arrow** button to view Insulin options.



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.

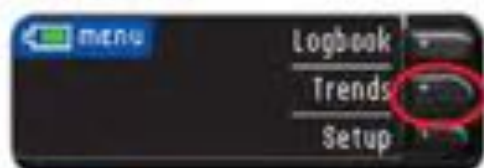
Trends

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.

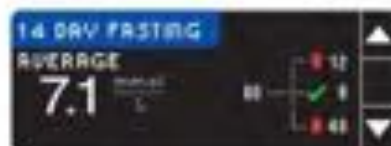
Viewing Trends with AutoLog On

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



You will see this summary screen.

2. Press the **Down Arrow** 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 \uparrow , within \checkmark and below \downarrow target.

3. Press the **Down Arrow** button to go to the 14 Day Before Meal Average.



This example shows that your Before Meal average is 7.1 mmol/L and 38 test results are included in the Before Meal average with 26 within \checkmark the target range, 8 above \uparrow the target range and 4 below \downarrow the target range.



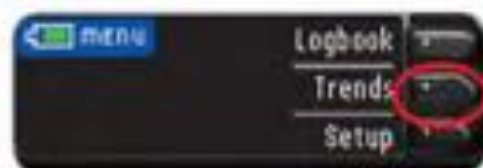
4. Press the **Down Arrow** button to go to the 14 Day After Meal Average.



5. Press the **Down Arrow** button to go to the 14 Day Results screen.

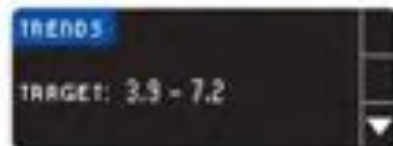
Viewing Trends with AutoLog Off

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

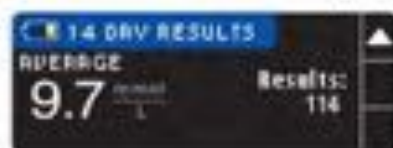


From the Main Menu, select Trends.

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 **Down Arrow** button to display the 14 Day Results screen.



Setup

You can change options on your meter and personalize 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.



Press the Setup button.



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

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.



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

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.



Press the
Setup button.

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



3. Select **Stop**.



Reminder is now off.



Setting the Date

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



Press the **OK** button.

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



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

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



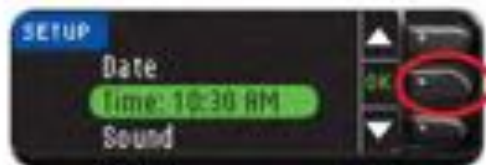
Press the **OK** button.

7. Press the **▲** or **▼** button to select the correct month.
Press the **OK** button.
8. Press the **▲** or **▼** button to select the correct day.
Press the **OK** button.

A screen confirms the date you entered. If correct, press the **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 **OK** button.



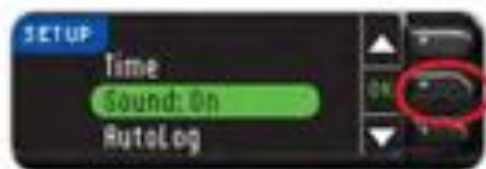
4. To change the time, press the **Change** button.
5. Select either the 12 hour clock or 24 hour clock button.
6. Press the **▲** or **▼** button to select the correct hour.
Press the **OK** button.
7. Press the **▲** or **▼** button to select the correct minute.
Press the **OK** button.
8. If you have 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 **Sound**.



Press the **OK** button.

4. To turn the sound off, press the **Left 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.



Press the **OK** button.

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

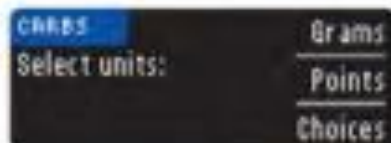


A screen confirms your choice. The Setup menu will appear.



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 not need to set these each time you use this feature, but can change them in the Setup menu.



1. Use the ▲ or ▼ 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:

- Before Meal: 3.9 - 7.2 mmol/L
- After Meal: 3.9 - 10.0 mmol/L
- Fasting: 3.9 - 7.2 mmol/L

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



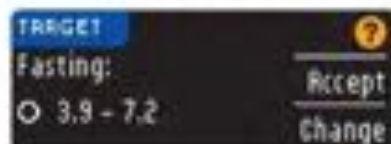
WARNING

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

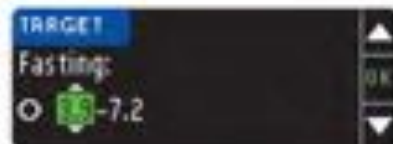
1. Press and hold the **Menu** button to turn the meter on.
2. Press the **Setup** button.
3. Press the ▼ button to select **Target**. Press **OK**.



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



5. Press the ▲ or ▼ button to select your desired Fasting targets. Press **OK**.



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

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



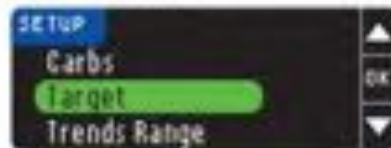
A screen confirms that all target ranges are set.

If correct, press the **Accept** 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.

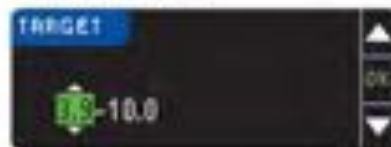


3. Press the ▼ button to select Target.



4. Select Change.

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

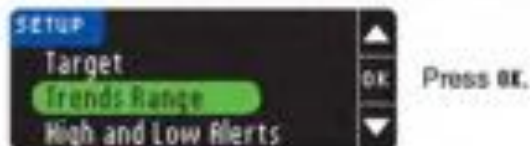


6. Press **OK**.
A screen confirms your choice.

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 **Mees** button to turn the meter on.
2. Press **Setup**.
3. Press the **▼** button to select **Trends Range**.



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.



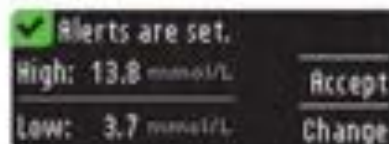
WARNING

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 13.9 mmol/L and the preset low alert is 3.9 mmol/L.



2. Choose **Change** if you wish to use different alert levels.
3. Press the **▲** or **▼** button to select your high alert. Press **OK**.
4. Press the **▲** or **▼** button to select your low alert. Press **OK**.
5. The next screen confirms your choices. Press **Accept**.



Setting the Language

1. Press the **Menu** button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the **▲** or **▼** button to select Language. Press the **OK** button.
4. Press the **▲** or **▼** button to select the language you prefer. Press **▼** to see more choices. Press the **OK** button.

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

Customer Service

This option is only 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 9 a.m. to 9 p.m. EST, seven days a week at 1-800-268-7200.

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:

1. 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 **OK**.
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.

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 colour 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.

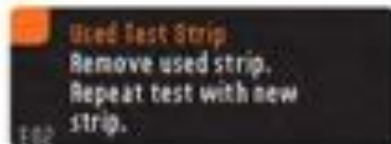
A GLUCOFACTS DELUXE User Guide is also available at www.bayerglucofacts.com.

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 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven days a week), or visit our website at www.bayerdiabetes.ca.

Error Detection Displays


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

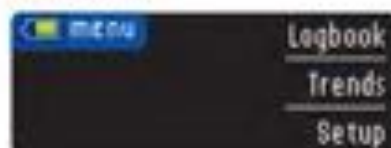


- If there is an error (hardware, software, testing errors) detected by your meter, your meter will beep twice.
- You will see specific instructions to guide you. The first line of the error screen will tell you the error. The next lines describe what you should do. When an error screen has an **E** shown, press the button next to it to continue.
- If you do not resolve the problem, contact Bayer Diabetes Care Customer Service at 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven days a week).

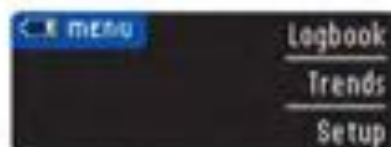
Battery Status

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." 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.

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.

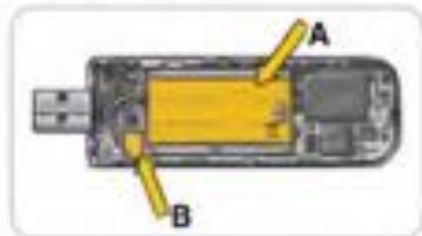
To remove the battery for proper disposal, you will need to pry the upper and lower cases apart.

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



Pry up rechargeable battery here (A).

Disconnect battery by pulling battery connector (B).



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

Symptoms of High and Low Blood Sugar

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

Low Blood Sugar (Hypoglycaemia)

- Shakiness
- Sweating
- Fast Heartbeat
- Blurred Vision
- Confusion
- Passing Out
- Irritability
- Seizure
- Extreme Hunger
- Dizziness

High Blood Sugar (Hyperglycaemia)

- Frequent Urination
- Excessive Thirst
- Blurred Vision
- Increased Fatigue
- Hunger

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 2.8 mmol/L or above 13.9 mmol/L, contact your health care professional immediately.

For additional information and a complete list of symptoms, contact your health care professional.

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 venous and 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).⁹

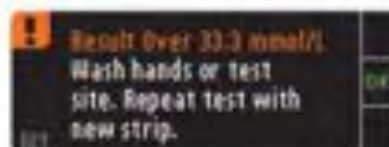
Measuring Range

Your meter's measuring range is 1.1 - 33.3 mmol/L.

- If your blood sugar reading is under 1.1 mmol/L, 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 33.3 mmol/L 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.



Accuracy

The CONTOUR[®]NEXT USB blood glucose monitoring system was tested on 100 capillary blood samples using CONTOUR[®]NEXT test strips. Two replicates were tested with each of three lots of CONTOUR NEXT test strips for a total of 600 readings. 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 USB meter using CONTOUR NEXT test strips at glucose concentration < 4.2 mmol/L.

Difference range in values between YSI laboratory reference method and CONTOUR NEXT USB meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	65 / 78 (83.3%)	78 / 78 (100%)	78 / 78 (100%)

Table 2 – System accuracy results for CONTOUR NEXT USB meter using CONTOUR NEXT test strips at glucose concentration ≥ 4.2 mmol/L.

Difference range in values between YSI laboratory reference method and CONTOUR NEXT USB meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Number (and percent) of samples within specified range	390 / 522 (74.7%)	512 / 522 (98.1%)	522 / 522 (100%)	522 / 522 (100%)

Acceptance criteria in ISO 15197:2003 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within 0.8 mmol/L for glucose values less than 4.2 mmol/L, and within 20% for glucose values greater than or equal to 4.2 mmol/L.

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 2.6 to 18.4. 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, mmol/L	Pooled Standard Deviation	Coefficient of Variation, %
2.6	0.05	1.8
4.8	0.07	1.5
7.3	0.11	1.5
11.7	0.15	1.3
19.0	0.35	1.9

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 1-800-268-7200 (available 9 a.m. to 9 p.m. EST, seven days a week). 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


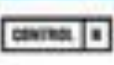






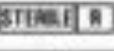





This check list may be helpful when speaking with Bayer Diabetes Care Customer Service:



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).

Symbol	What it Means	Symbol	What it Means
	Use by date (last day of month)		Control Range Normal
	Batch code		Control Range Low
	Temperature limitations		Control Range High
			Do not reuse
	Consult instructions for use		Sterilized using irradiation
	In Vitro Diagnostic Medical Device		Caution
	Catalogue number		Recycle Packaging
			Certified USB-IF

Symbol	What it Means
	Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area. The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment.
	The USB cable is waste electrical and electronic equipment. Do not dispose in household waste. Remember to respect local regulations.

Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.

System Specifications

Test Sample: Capillary and venous whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 1.1 - 33.3 mmol/L

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

Strip Storage Temperature Range: 5°C - 30°C

Normal Control Storage Temperature Range: 5°C - 30°C

Meter Operating Temperature Range: 5°C - 30°C

Humidity: 10–93% RH

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

Weight: 43 grams

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.bayerdiabetes.ca

References

1. Wickham NWR, Achar KN, Cover DH. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
2. Atkin, S. et al. Fingertick 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. Health Canada Advisory : Blood Lancing Devices for Personal Use May Transmit Blood-Borne Viruses if Used On More Than One Person (2009) http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_50-eng.php
5. Longo D.L. et al. *Harrison's Principles of Internal Medicine*, 18th Edition, 2011. <http://www.accessmedicine.com>

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 1-800-268-7200 (9 a.m. to 9 p.m. EST, seven days a week), for a replacement.
- Your meter should be cleaned and disinfected once a week. For cleaning and disinfection instructions, see pages 26-29.



WARNING: Potential Biohazard

The CONTOUR[®]NEXT USB system is not intended for use on multiple patients. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases. The user should follow the recommendations for prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens prior to repair service or investigation.

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 Normal Control Solution (2 vials)
CONTOUR NEXT Low Control Solution (1 vial)
CONTOUR NEXT High Control Solution (1 vial)
CONTOUR[®]NEXT Test Strips 50's
CONTOUR NEXT Test Strips 100's
MICROLET[®]2 Lancing Device
MICROLET[®] Lancets (box of 100's)
MICROLET Lancets (box of 200's)

Check the website www.bayerdiabetes.com for any meter updates or GLUCOFAC[®] DELUXE updates.

To order parts, please call Bayer Diabetes Care Customer Service at 1-800-268-7200, 9 a.m. to 9 p.m. EST, seven 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 GLUCOFAC[®] 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.

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

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84318354 Rev. 07/12

