



Uses only CONTOUR®NEXT blood glucose test strips from Bayer

USER GUIDE

INTENDED USE

The CONTOUR®NEXT LINK wireless blood glucose monitoring system from Bayer (meter, test strips and control solution) is intended for self-testing by persons with diabetes to monitor glucose concentrations for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertip or palm. It is intended for *in vitro* diagnostic use only. The clinical utility of this device is that it may be used as an aid to monitor the effectiveness of a diabetes control program.

The CONTOUR NEXT LINK wireless blood glucose monitoring system is intended to be used to transmit glucose values to compatible Medtronic devices and facilitate transfer of information to Medtronic CareLink® Software through use of radio frequency communication.

The CONTOUR NEXT LINK wireless blood glucose monitoring system from Bayer is not intended for the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates.

IMPORTANT SAFETY INFORMATION



Serious Illness

- Capillary (fingerstick or Alternative Site) blood glucose testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycaemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.¹⁻³
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.

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 and dry 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 person use. Do not share them with anyone including other family members. Do not use on multiple persons.⁴
- All parts of this kit are considered biohazardous and can
 potentially transmit infectious diseases, even after you have
 performed cleaning and disinfection. For instructions, please see
 Cleaning and Disinfection, page 66.
- The MICROLET®2 lancing device is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.
- Use a new MICROLET® lancet each time you test because it is no longer sterile after use.
- Always dispose of test strips and lancets as medical waste or as advised by your health care professional. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.



PRECAUTIONS

- Ti Read your CONTOUR®NEXT LINK user guide, the MICROLET®2 lancing device package insert, your Medtronic device user guide 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.
 For replacement parts, contact Bayer Customer Service. Please see back cover for contact information.
- The CONTOUR NEXT LINK meter from Bayer only works with CONTOUR®NEXT test strips and CONTOUR®NEXT control solutions.
- 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, and dirt. Exposure to room humidity from 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 expiry dates on your test strips and control solution. Do not use the test strips or control solution if the expiry 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 6 months since you first opened the bottle. After first opening the bottle, write the 6-month discard date on the control solution label.
- If your control solution test result is out of range, contact Bayer Customer Service. Please see back cover for contact information. 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° to 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.
- Do not perform a blood glucose test when the CONTOUR NEXT LINK meter is connected to a computer.

- Use only approved cables or wall charger from the manufacturer or a 5V charger approved by a certified body such as UL, TUV or CSA.
- The CONTOUR®NEXT LINK meter from Bayer has been preset and locked to display results in mmol/L (millimoles of glucose per litre of blood).
 - * Results in mmol/L will always have a decimal point;
 - * Results in mg/dL will never have a decimal point.

Example: $5.2^{\frac{mmol}{L}}$ or $93^{\frac{mq}{dL}}$

- Check your display screen to be sure the results are shown the right way. If not, please see Bayer Customer Service contact information on the back cover of this user guide.
- The CONTOUR NEXT LINK wireless blood glucose monitoring system from Bayer has a measuring range of 1.1 mmol/L to 33.3 mmol/L.
 - * For results under 1.1 mmol/L or over 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.
 - 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 is available. If you wish to test immediately
 after disconnecting from your computer, please use the USB
 cable to protect the meter from exposure to heat created by the
 computer.

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

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Rechargeable Battery

The CONTOUR®NEXT LINK meter from Bayer 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.

Charge Your Meter Using a Wall Outlet or a Computer



- Remove USB cap.
- Insert the meter USB plug into the wall charger* or use the USB extension cable.

The meter is fully charged when the test strip port light stops flashing and turns off.

*Charger is available separately from Bayer Customer Service if not included in your meter kit. See contact information for Bayer Customer Service on back cover

CAUTION: Do not perform a blood glucose test when your meter is connected to an external device, e.g., computer.

NOTE: Your meter can Rapid Charge. After 1 minute of charging, you can unplug the meter and run one blood sugar test, if needed. A USB extension cable is included for your convenience.



OR

- Remove USB cap.
- Insert the meter USB plug into your computer or use the USB extension cable.
- Be sure your computer is turned on and not in sleep, hibernate, or power save mode.

CAUTION: 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 to protect the meter from exposure to heat created by the computer.

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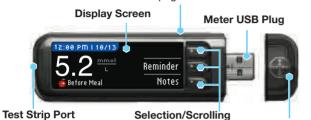
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Getting Started

The CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System from Bayer

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

Top Menu Button See page 4



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

Selection/Scrolling Buttons See page 4

Protective USB Cap

WARNING

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

Your CONTOUR NEXT Test Strip

Grey Square End

Insert this end into the test strip port with the grey end facing up.

Sample Tip

Blood sample pulled in here.

CAUTION: The CONTOUR NEXT LINK meter from Bayer only works with CONTOUR NEXT test strips and CONTOUR®NEXT control solutions.



"Talks" to Your Compatible Medtronic Device

Your CONTOUR®NEXT LINK meter can automatically send your blood glucose result directly to your compatible Medtronic device, if your meter and pump are linked. This eliminates the need to manually enter your blood glucose result into your insulin pump. Your compatible Medtronic device will only accept the glucose result if the Meter Send Option in your device's Utility Menu is set to On and you have programmed the device with the meter's ID (serial) number. Up to 3 CONTOUR NEXT LINK meters can be connected to your Medtronic pump. To use the meter link features, your CONTOUR NEXT LINK meter and Medtronic device must be within 1.22 meters of each other. If you are not using the meter link feature, you may want to set the Send Option to Never on your CONTOUR NEXT LINK meter to save battery power.



GETTING STARTED

Your MICROLET®2 Lancing

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.
- Meter turns off after 3 minutes of inactivity.

Using the Top Menu Button



The top **Menu** button has three functions:

- To turn the meter on/off, press and hold the top Menu button.
- To go back one screen from most screens, press the top Menu button once.
- To turn on/off the test strip port light, quickly press the top Menu button two times.

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.
- 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 0K.

NOTE: Press and hold the ▲ or ▼ button to scroll through the list faster.

Using the Main Menu



The Main Menu has three choices: Logbook, Trends and Setup. Select one by pressing the button next to your choice.

CAUTION: Unplug meter from charging source before beginning Setup.

Initial Setup



1. Before use, fully charge your meter. See page vi.

Turn On



2. Press and hold the top Menu button until the meter turns on. After a welcome screen, you see the Language choice screen.



GETTING STARTED

Initial Setup

GETTING STARTED

Set Language



 Press the ▼ button to see more language choices. When your language is highlighted, press 0K.



4. Press OK to confirm.

If the correct language is not displayed, press No.

Connect to Pump



5. If you are connecting to a MiniMed® pump now, press 0K and go to Step 6. If not, press \$KIP and go to Step 17.

NOTE: Pump refers to your compatible Medtronic device.

connect to pump Enter this Meter ID into your Pump: 123456



6. STOP. Do <u>NOT</u> press <u>ANY</u> buttons.

This screen displays the meter ID (in the bottom left corner). This ID is needed to complete the connection process.

Put down your meter. Pick up the compatible Medtronic device and continue with Step 7.



 Press ACT to go to the MAIN MENU. Scroll to Utilities by pressing the down arrow. Press ACT.



DEVICE OPTIONS
Meters
Remotes
Other Devices

8. Scroll to Connect Devices and press ACT.

Then scroll to Meters and press ACT.

NOTE: If your UTILITIES MENU does not contain Connect Devices, scroll to Meter Options and press ACT.



- Select 0n and press ACT. If you are replacing a meter, go to Step 10. If you are adding a new meter, go to Step 12.
- METER ID MENU Add ID Delete ID Review ID
 - **10.** To replace a meter, select **Delete ID** and press **ACT**.



11. If you have multiple meter IDs, repeat Step 10 for each one.





12. To add a new meter, select fldd ID and press ACT. Refer to Step 6 (or see meter back) to find meter ID (SN).
Use the up and down arrow buttons to

enter the six character meter ID shown on the meter screen.

Press **ACT** after each character entry.



GETTING STARTED



13. Select Review ID on your compatible Medtronic device to confirm that your CONTOUR®NEXT LINK meter ID has been correctly entered. If incorrect, go back to Step 10.



NOTE: For detailed instructions, see your compatible Medtronic device user guide.



14. Return to your
CONTOUR NEXT LINK
meter. After you have
entered the meter ID
into your compatible
Medtronic device,
press Next.

Meter Send Options

15. After the meter and pump are connected, you set your Send Options. This controls how your meter sends blood glucose readings to your Medtronic pump. Your options are:

Always Meter will always send results		Meter will always send results
Ask Me Meter will ask you before sending res		Meter will ask you before sending results
Never Meter will never send res		Meter will never send results





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

Your choice can be changed later using Setup (see page 42).

16. Press 0K.

Set Date and Time to Match Medtronic Device



17. The date and time on your meter must match the date and time on your Medtronic device. Pick up Medtronic device. Press ACT to go to the MAIN MENU. Scroll to Utilities and press ACT. Scroll to Time/

Date and press **ACT**. Select a time format and press **ACT**. Note the time and date.

Return to your **meter**. Follow instructions on your meter to change the time and date to match your **Medtronic device**.

AutoLog

The AutoLog feature lets you mark your test result as



Your meter comes preset with AutoLog turned OFF.



18. When the AutoLog screen appears, press Accept to keep AutoLog OFF. Or, to activate AutoLog, select Turn On.



High and Low Alerts

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

NOTE: Alerts can only be set outside your selected Target Range(s). For additional information, you may contact Customer Service. Contact information for Customer Service is on the back cover.

MARNING

Talk to your health care professional before setting any High or Low Alerts on your meter.

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.



19. Select Accept to keep the preset alert levels. If you wish to change these alert levels, press Change.

NOTE: Your Target ranges must be within your High and Low Alert levels. You set your Target ranges next.



20. 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.



21. Press the ▲ or ▼ button to select your Low Alert level. This can be set between 3.0 - 5.5 mmol/L. Press 0K.

GETTING STARTED

Target Ranges

NOTE: Press and hold the ▲ or ▼ button to scroll through the numbers faster.



22. The next screen confirms your choices. Press

Accept to confirm your Alert settings.

Target Ranges

Next you are asked to accept your blood sugar Targets. Targets are your personal ranges for your blood sugar results. With AutoLog OFF, you have a single Target range. With AutoLog ON, you have Target ranges for Fasting, Before Meal, and After Meal.

NOTE: Targets can only be set inside your selected Alert level(s). For additional information, you may contact Customer Service. Contact information for Customer Service is on the back cover.

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



23. If AutoLog is OFF, Accept or Change the preset blood sugar Target range. The preset range is 3.9 - 10.0 mmol/L.



If AutoLog is ON, Accept or Change the preset blood sugar range for Fasting, Before Meal, and After Meal

screens. Each Target has an option to Accept or Change.

NOTE: As shown in the meter screen above, the preset values of 3.9-7.2 are based on ADA recommendations.⁵

The values based on Canadian Diabetes Association (CDA) recommendations are as follows:⁶

0	Fasting	4.0 - 7.0 mmol/L
6	Before Meal	4.0 - 7.0 mmol/L
Î	After Meal	5.0 - 10.0 mmol/L



24. To change the Targets press the ▲ or ▼ button until the desired Target is reached and then press OK. Press Accept on confirmation screen.

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



Initial Setup is complete. You may now test your blood sugar. See Testing, below.

Testing

Getting Ready to Test

Ti Read your CONTOUR®NEXT LINK user guide, your Medtronic device 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.

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 Customer Service for replacement parts. Please see back cover for contact information.

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

Have all the materials you need ready before you begin testing. This includes your CONTOUR NEXT LINK meter, CONTOUR NEXT test strips, and the MICROLET®2 lancing device and MICROLET® lancets. You may also need CONTOUR NEXT control solution to perform a quality control check. CONTOUR NEXT control solutions are available separately if not included in the meter kit.

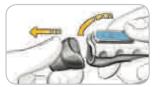
- Do not perform a blood glucose test when your meter is connected to an external device, e.g., computer.
- Use only approved cables or wall charger from the manufacturer or a 5V charger approved by a certified body such as UL, TUV or CSA.

Preparing the Lancing Device

WARNING: Potential Biohazard
The MICROLET 2 lancing device is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.

② Use a new MICROLET lancet each time you test because it is no longer sterile after use.

Read the MICROLET 2 lancing device insert for complete instructions. If you are using a different lancing device, see that manufacturer's instructions for use. For Alternative Site Testing instructions, see page 19.



 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.



TESTING

Lancing Devic





operation.

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.

2. Loosen the round protective cap on the lancet by rotating

it. Always use MICROLET®

lancets for the best

it 1/4 turn, but do not remove



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



5. Replace the grey endcap before getting blood drop.



6. The puncture depth depends on the endcap setting and the amount of pressure applied to the puncture site. Rotate the endcap dial to adjust the puncture depth.

Preparing the Test Strip



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



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



- 2. Hold the test strip with the grey square end facing up.
- Insert the grey square end into the test strip port until the meter beeps (if the Sound is set to ON).



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

NOTE: 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.

Getting the Blood Drop — Fingertip Testing



1. Press the endcap firmly against the puncture site and press the blue release button with your thumb.



Stroke your hand and finger toward the puncture site to form a drop of blood. Do not squeeze around the puncture site. TESTING

Blood Drop

Apply More Blood

TESTING



Test immediately after a good drop of blood has formed.



 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.

Apply More Blood



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

I Too Little Blood
Remove used strip.
Repeat test with new
E01 Strip.

If you do not re-apply enough blood within about 30 seconds, you will see a screen telling you to remove the strip and repeat with a new strip.

Test Results

Testing With AutoLog Off



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





If filways was selected in Send Options during Setup, your result is automatically sent to your pump. If Never was selected in Send

Options, you will not have the option to send the result to your pump. If fisk Me was selected in Send Options, you can choose to send your result to your pump after each blood sugar test.

Press Send or Don't Send. If Send is chosen, press OK on the Send confirmation screen

Leave the test strip in the meter to set an optional reminder for your next test (see page 31) or add a note (see page 34).



If you are done, remove the test strip from the meter. Press and hold the top **Menu** button to turn off the meter. The meter also turns off after 3 minutes of inactivity.

CAUTION: Always check the display on your pump to ensure that the glucose result shown agrees with the glucose result shown on the meter.



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TESTING

Testing With AutoLog On



After you apply blood to the test strip, use the ▼ to select Fasting, Before Meal, After Meal, or No Mark, and then press OK. (Scroll down to see No Mark.)

NOTE:

- Your test result does not display until you make an AutoLog selection.
- If your result is above or below your High or Low Alert settings, you will see your result without pushing a button.

O Fasting	The Fasting marker can be used when testing blood sugar levels after going without food and sugared drink for 8 hours.	
6 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.	

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

9.3

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



If filways was selected in Send Options during Setup, your result is automatically sent to your pump. If Never was selected in Send

Options, you will not have the option to send the result to your pump. If #sk Me was selected in Send Options, you can choose to send your result to your pump after each blood sugar test. Press Send or Don't Send. If Send is chosen, press OK on the Send confirmation screen.

Leave the test strip in the meter to set a reminder for your next test (see page 31) or add a note (see page 34).



If you are done, remove the test strip. To turn off the meter, press and hold the top **Menu** button. Or, after 3 minutes of inactivity, the meter turns off automatically.

CAUTION: Always check the display on your pump to ensure that the glucose result shown agrees with the glucose result shown on the meter.

Alternative Site Testing (AST) — Palm

/ WARNING

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

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



Getting a Blood Drop for Alternative Site Testing

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 (hypoglycaemic 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 test 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 testing results may identify hypoglycaemic 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 endcap to perform AST, contact Bayer Customer Service. Please see back cover for contact information.

Getting a Blood Drop for Alternative Site Testing



- 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.



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



 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.



- Lift the device straight up and away from the skin without smearing the blood.
- **7.** Test immediately after you have formed a small, round blood drop.

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

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

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



8. Hold the tip of the test strip in the blood drop until the meter beeps. Do not press the tip against the skin or place the blood on top of the test strip or you could get inaccurate results or errors.





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

I Too Little Blood
Remove used strip.
Repeat test with new
E81 strip.

If you do not apply more blood within about 30 seconds, remove the strip and repeat with a new strip.



9. If you have the AutoLog feature turned ON, the AutoLog screen appears. Select O Fasting, Before Meal, Rifter Meal, or No Mark by pressing the OK button when your selection is highlighted. Scroll down to see No Mark.

NOTE:

- Your test result does not display until you make an AutoLog selection.
- If your result is above or below your High or Low Alert settings, you will see your result without pushing a button.



If filways was selected in Send Options during Setup, your result is automatically sent to your pump. If Never was selected in Send

Options, you will not have the option to send the result to your pump. If Rsk Me was selected in Send Options, you can choose to send your result to your pump after each blood sugar test. Press Send or Don't Send. If Send is chosen, press OK on the Send confirmation screen. You can change your send option at any time using the Setup Menu (see page 42).

! WARNING

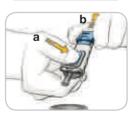
- Do not calculate a bolus based on an AST result.
- Do not calibrate your continuous glucose monitoring device from an AST.

If you are done, remove the test strip from the meter. Press and hold the top **Menu** button to turn off the meter. The meter also turns off after 3 minutes of inactivity.

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 exposed side of the cap.



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

NARNING

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

TESTING

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WARNING: Potential Biohazard

- Always dispose of test strip and lancet as medical waste or as advised by your health care professional.
 All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Please refer to your MICROLET®2 package insert for instructions on how to properly remove and dispose of the lancet.

Test Results — Expected Values

Blood glucose 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, approximately 3.9 - 6.1 mmol/L in a fasting state.⁷



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

- 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.

High and Low Blood Sugar Alert Screens

Your meter has been preset with a low blood sugar (hypoglycaemia) value of 3.9 mmol/L and a high blood sugar (hyperglycaemia) value of 13.9 mmol/L. These are the preset values, but can be customized by you and/or your health care professional. You can change the High and Low Alert levels under Main Menu, Setup option (see page 52).

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



 A screen with large orange numbers alerts you that your blood sugar is low.

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



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



TESTING

High and Low Blood Sugar Alert Scree



 If AutoLog is ON and you did not mark your result before the high or low alert appeared, select Notes.



- Press the ▲ or ▼ button to scroll through the choices.
- Press **0K** when your choice is highlighted.



NOTE: If the highlight is over an item that has previously been selected, you will see a red "X" instead of "OK."

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 top **Menu** button two quick presses to turn on the test strip port light.
- Insert a test strip and the display screen appears.
- Once blood is applied to the test strip, the light goes off.
- Continue with your test.
- Two quick presses of the top Menu button also turns off the light.

Control Solution Testing

MARNING

Shake the control solution well before testing.

CAUTION: Use only CONTOUR®NEXT control solution from Bayer (Normal, Low and High) with your CONTOUR®NEXT LINK blood glucose monitoring system. Using anything other than CONTOUR NEXT control solution can cause inaccurate 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 correctly
- you have repeated, unexpected blood glucose results

/ WARNING

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

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

Normal, Low and High control solutions are available separately if not included in the meter kit. Always use CONTOUR NEXT

control solutions from Bayer. Other brands could present incorrect results. If you need help locating CONTOUR NEXT control solutions from Bayer, contact Bayer Customer Service. Please see back cover for contact information.

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



TESTING

Control Solution Testing

Control Solution Testing

TESTING



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



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



- Shake the control solution bottle well before every use.
- Remove bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
- 7. Squeeze a small drop of control solution on a clean nonabsorbent surface

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



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



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

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



- **11.** Compare your control test result to the ranges printed on the test strip bottle.
- 12. Remove test strip. To turn the meter off, press and hold the **Menu** button, OR, after 3 minutes of inactivity, the meter turns off. Dispose of the used test strip as medical waste or as advised by your health care professional.

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

NARNING

- If the control solution test result is out of range, the result may be transmitted to your pump when in "Always" send mode (see page 30).
- Do not send an out of range control result to your pump.

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



Features

Your CONTOUR®NEXT LINK meter includes many testing features.

AutoLog (Marking Your Results)

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

Your meter comes with AutoLog OFF. If you would like to see your results when Fasting, Before Meal or After Meal, we recommend that you turn on this feature (see page 47).



If you have turned AutoLog ON in Setup, before your test result is displayed, the AutoLog screen appears. However, if your result is above your High Alert setting or below your Low Alert setting, you will always see your result in 5 seconds without pushing a button.

Sending Results to Your Pump

You can send your results to the pump during testing. During Initial Setup (Send Options) or in Setup (Pump Options - Send Options), choose fisk Me or filways.



If filways was selected in Send Options during Setup, your result is automatically sent to your pump. If Never was selected in Send

Options, you will not have the option to send the result to your pump. If **fisk Me** was selected in Send Options, you can choose to send your result to your pump after each blood sugar test.

Press **Send** or **Bon't Send**. You can change your Send Option at any time using the Setup Menu (see page 42).

CAUTION:

- You may want to test with Send Options set to Never if you do not want to create a wireless signal (for example, if you have been asked to turn off all electronic devices in an aircraft).
- Always check the display on your pump to ensure that the glucose result shown agrees with the meter display.

Test Reminders

A reminder for your next test can be set after testing OR from the Setup Menu (see page 43).

A reminder can be set in 15-minute increments from 15 minutes to 23 hours, 45 minutes.

Setting a Test Reminder



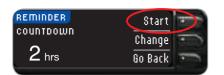
1. With the test strip still in the meter, press Reminder.



OR from the Setup Menu press the ▼ button to highlight Reminder: Off. Press OK to turn the Reminder ON.

FEATURES

Test Reminders



2. Press \$tart
to begin the
countdown. The
preset time is
2 hours or, if you
have changed it,
the last reminder
time that you set
is now the default.



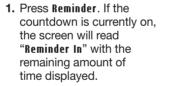
You can change the Reminder Countdown time by pressing Change.

Turning Off a Test Reminder

A reminder can be turned off or changed after testing or from the Setup Menu.

NOTE: If you do a blood sugar test within 15 minutes of a set reminder, the reminder turns off automatically.







2. To stop the countdown, press \$top.

A confirmation screen appears and the countdown stops.

Changing a Reminder Time

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



2. Press **OK** after each selection.



A screen confirms the reminder countdown time.

When the Reminder feature is on, the clock symbol appears in the headers on the Setup and Main Menu screens.

The meter retains the reminder time that you set until you change it or turn it off.

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:



- Press OK, insert a test strip and proceed with testing, OR
- Insert a test strip and proceed with testing (see page 12).

NOTE: If you decide to test within 15 minutes before the reminder time, the countdown is stopped with the insertion of the test strip. Proceed with testing.



FEATURES

Changing a Reminder Time

Notes

ADD NOTES

Sick

Stress

Activitu

Go Back

Before Meal

Time After Meal

Don't Feel Right

After Meal

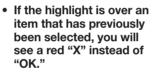
You may add notes to your test result that may help explain results. Your notes will be saved in the Logbook. The option to add a note is available only after a test result.

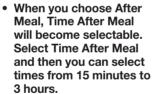
1. From the test result screen, press Notes.



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

NOTE:





After the confirmation screen disappears, you may remove the note or add one or more notes by repeating the steps above. The notes will scroll across the bottom so that you can read them all. While you can add more than one note, only one AutoLog option can be chosen (e.g., Fasting, Before Meal or After Meal).

Using the Main Menu

The Main Menu has three choices: Logbook, Trends, and Setup. Select one by pressing the button next to your choice.



Logbook

The Logbook contains blood sugar test results and notes that you have made to those test results. The Logbook will hold up to 1,000 results. When the maximum is reached, the oldest test result will be removed as a new test is completed and saved to the Logbook. A sound indicates the last entry.

- To review entries in the Logbook, press and hold the top Menu button to turn the meter on.
- 2. Press the button next to Logbook.





 You can scroll through all your stored test results using the ▼ button.

When you reach the oldest entry you will see the End of Logbook screen.



Logbook

Trends (Averages and Summaries)

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 averages. Your meter has been preset to 14 day averages, but you can change this under Trends Range in the Setup Menu (see page 51).

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

Your screen will display the total number of test results included in the average and the number of tests above ♠, within ✔ and below ♣ Target.

Viewing Trends With AutoLog Off

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

- 1. Press and hold the top **Menu** button to turn the meter on.
- 2. Press the button next to Irends.



3. Press the ▼ button to display the 14 Day

Results screen.

Viewing Trends With AutoLog On

- 1. Press and hold the top **Menu** button to turn the meter on.
- 2. Press the ▼ button to highlight Irends. Press OK to select.



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



 Press the ▼ 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 ✓ the Target range, 8 above ↑ the Target range and 4 below ↓ the Target range.



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



Press the ▼ button to go to the 14 Day Results screen. Viewing Trends With AutoLog Or

MAIN MENU

Setup

You can view and change options on your meter and personalize it from the Setup Menu.

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



The current settings in the meter for the Reminder, Date, Time, Sound and Rutolog can be viewed by scrolling through the Setup Menu items. To view the settings of the other items, or to make any changes to any of the items, you can select the item using the ▲ and ▼ keys and pressing OK.

Pump Options

Pump Options allows you to connect to a Medtronic pump and change your Send Settings (how your blood sugar readings are sent to your pump).

Connecting the Meter and Pump

You can send blood sugar results to your pump if your meter and pump are connected.

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



3. Press OK to select Pump Options.

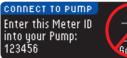


4. Press Connection.



5. Press **0K** to begin the connection process.

NOTE: Pump refers to your compatible Medtronic device.



6. STOP. Do <u>NOT</u> press ANY buttons.

This screen displays the meter ID number (in the bottom left corner). This ID is needed to complete the connection process. Put down your meter. Pick up the compatible Medtronic device and continue with Step 7.



7. Press ACT to go to the MAIN MENU.
Scroll to Utilities by pressing the down arrow. Press ACT.





8. Scroll to Connect Devices and press ACT.



Then scroll to Meters and press ACT.

NOTE: If your UTILITIES MENU does not contain Connect Devices, scroll to Meter Options and press ACT.



 Select 0n and press ACT. If you are replacing a meter, go to Step 10. If you are adding a new meter, go to Step 12.



To replace a meter, select Delete ID and press ACT.



11. If you have multiple meter IDs, repeat Step 10 for each one.



ADD METER ID

12. To add a new meter, select fidd ID and press ACT. Refer to Step 6 (or see meter back) to find meter ID (SN).
Use the up and down arrow buttons to enter the six character meter ID shown on the meter screen.

on the meter screen.

Press **ACT** after each character entry.





13. Select Review ID on your compatible Medtronic device to confirm that your CONTOUR®NEXT LINK meter ID has been correctly entered. If incorrect, go back to Step 10.



NOTE: For detailed instructions, see your compatible Medtronic device user guide.



- 14. Return to your
 CONTOUR NEXT LINK
 meter. After you have
 entered the meter ID
 into your compatible
 Medtronic device,
 press Next.
- 15. After the meter and pump are connected, you set your Send Options. This controls how your meter sends blood glucose readings to your Medtronic pump. Choose the Send Option that is best for you.

Your options are:

Always Meter will always send results	
fisk Me Meter will ask you before sending resu	
Never	Meter will never send results



To change your choice, see page 42.



Connecting the Meter and Pump



 The next screen confirms your Send Option choice. Press OK.

NOTE: If you want to disconnect the pump from the meter, you do not need to take action on your meter. Please refer to your Medtronic device user guide.

Changing the Send Option

Send Options control how your meter sends your test results to your pump. You have 3 choices:

Always Meter will always send results	
Ask Me Meter will ask you before sending result	
Never	Meter will never send results

NOTE: You may want to test with the Send Option set to Never if you do not want to create a wireless signal (for example, if you have been asked to turn off all electronic devices on an aircraft).

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



 Press the ▼ button to highlight Pump Options. Press OK to select.



4. Press Send Options.

NOTE: For Connection settings, see page 38.



To change the current Send Option, press Change.



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



A confirmation screen appears. Press OK to return to Pump Options.

Test Reminders

A reminder for your next test can be set after testing or from the Setup Menu. See page 31 for Setting a Test Reminder after Testing.

Setting a Reminder

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





- Press the ▼ button to highlight Reminder: Off.
 Press OK to turn ON the reminder.
- 4. To accept the preset time shown, select \$tart. To change the time, select Change. Use the ▲ and ▼ buttons to change the reminder time in 15-minute increments from 15 minutes to 23 hours, 45 minutes.



Test Reminders



 After you have selected hours, press OK. After you have selected minutes, press OK.



A confirmation screen appears and you can select Change or Done.

If you accept the reminder, a reminder icon ② will appear in the Setup and Main Menu headers.

NOTE: If you decide to test within 15 minutes before the reminder time, the countdown stops when you insert a test strip.

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 top **Menu** button to turn the meter on.
- 2. Press the button next to Setup.



3. Press the ▼
button to highlight
Reminder: On.
Press OK to turn
the Reminder OFF.



4. Select Stop. A confirmation screen appears and the countdown stops.



5. Reminder is now off.

Date and Time Setting or Changing the Date

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



3. Press the ▼ button to highlight Date. Press OK to select.



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



Select either format, Month/Day/Year or Day.Month.Year.



 Press the ▲ or ▼ button to select the correct year, month and day. Press 0K after each selection.



7. A screen confirms the date you entered. Press **Done** if the date is correct.



Date and Time

Setting or Changing the Time

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



 Press the ▼ button to highlight Time. Press OK to select.



4. To change the time, press **Change**.



5. Select either the 12 Hour Clock or 24 Hour Clock option.



- Press the ▲ or ▼ button to select the correct hour and minute. Press 0K after each selection.
- If you have selected the 12 hour clock format, press the ▲ or ▼ button to select AM or PM.



8. Time is set. A screen confirms your choice. Press **Done**.

Sound

Turning the Sound On/Off

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

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



Press the ▼ button to select Sound. Press OK.



 To turn the sound OFF, press Turn Off. To keep the sound turned ON, press Accept.



A screen confirms your choice.

AutoLog

NOTE: Your meter comes with AutoLog turned OFF.

The AutoLog feature lets you mark your test result as



To Turn On AutoLog

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

Sound

MAIN MENU

AutoLog



 Press the ▼ button to highlight flutoLog. Press OK to select.



Press Turn On to activate AutoLog.



A screen confirms your choice.

NOTE:

- When you change your AutoLog setting to ON, you are asked to confirm your Target settings for Fasting, Before Meal and After Meal.
- Your test result does not display until you make an AutoLog selection.
- If your result is above or below your High or Low Alert settings, you will see your result without pushing a button.

To Turn Off AutoLog

NOTE: Your meter comes with AutoLog OFF.

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



 Press the ▼ button to highlight fluteLeg. Press 0K to select.



To turn AutoLog OFF, press Turn Off.



A screen confirms your choice.

NOTE: When you change your AutoLog setting to OFF, you are asked to confirm your Target setting.

Blood Sugar Targets

Targets are your personal ranges for your blood sugar results. With AutoLog OFF, you have a single Target range. With AutoLog ON, you have Target ranges for Fasting, Before Meal, and After Meal.

/ WARNING

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

Changing Targets With AutoLog Off

When AutoLog is OFF, you have only one Target range. It comes preset to 3.9 - 10.0 mmol/L.

NOTE: Targets can only be set inside your selected Alert level(s). For additional information, you may contact Customer Service. Contact information for Customer Service is on the back cover.

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



 Press the ▼ button to highlight Target. Press OK to select.



4. To make changes to your Target range, press **Change**.



 Use the ▲ or ▼ button to change each value of the Target. Press OK after each selection.



A screen confirms your choice.

Changing Targets With AutoLog On

When AutoLog is ON, your CONTOUR®NEXT LINK meter comes preset with the following Target ranges for testing:

0	Fasting	3.9 - 7.2 mmol/L
6	Before Meal	3.9 - 7.2 mmol/L
Ŷ	After Meal	3.9 - 10.0 mmol/L

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

NOTE: Targets can only be set inside your selected Alert level(s). For additional information, you may contact Customer Service. Contact information for Customer Service is on the back cover.

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



 Press the ▼ button to highlight Target. Press OK to select.



 To make changes to your Fasting Target range, press Change, otherwise press Accept.



- Press the ▲ or ▼ button to select your desired Fasting Targets. Press 0K after each selection.
- **6.** Repeat this process to set your personal Before Meal Targets and After Meal Targets.
- 7. Press OK after each selection.



A screen confirms that all Target ranges are set.

If correct, press **Done** to return to the Setup Menu.

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

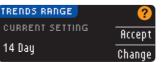
Trends Range

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 averages. Your meter has been preset to 14 day averages, but you can change this in Setup.

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



- 3. Press the ▼ button to highlight Irends Range.
- 4. Press OK to select.



5. Your current setting is displayed. You can Accept or Change your current setting.

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



Trends

Range



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

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. Results above High are marked High Blood Sugar. Results below Low are marked Low Blood Sugar.

NOTE: Alerts can only be set outside your selected Target Range(s). For additional information, you may contact Customer Service. Contact information for Customer Service is on the back cover.

WARNING

Talk to your health care professional before setting any High or Low Alerts on your meter.

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



3. Press the ▼ button to highlight High and Low Alerts. Press OK to select.



- 4. Choose Accept to use the preset Alert levels (or the Alert levels you chose during initial setup) for High and Low Alerts. The preset High Alert is 13.9 mmol/L and the preset Low Alert is 3.9 mmol/l
- 5. Choose Change if you wish to use different Alert levels.





- 6. Press the ▲ or ▼ button to select your High and Low Alert, Press NK after each selection
- 7. The next screen confirms vour choices. Press Done.

Set Language

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



- 3. Press the ▼ button to highlight Language. Press **OK** to select.
- LANGUAGE English Deutsch Español
- 4. Press the ▲ or ▼ button to select the language you prefer. Press ▼ to see more choices. Press 0K.



5. Verify that the language you selected is displayed. Press **NK** to confirm. If the correct language is not displayed, press No.

Customer Service

This option is to be used if you are speaking to a Bayer Customer Service representative. They will give you a code that enables them to verify certain settings. It is not for use any other time. Please see back cover for contact information.



Set Language

TECHNICAL CARE

Error Detection Displays

Technical and Care

Transferring Data to Medtronic's CareLink®



Personal Therapy Management Software

You can easily transfer blood glucose results from your meter to CareLink Personal Therapy Management software.

You can also wirelessly transfer data from your compatible pump

to CareLink Personal Therapy Management software using your ${\tt CONTOUR}^{\circledast}{\tt NEXT}$ LINK meter.

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

Your CONTOUR NEXT LINK meter is also compatible with GLUCOFACTS DELUXE diabetes management software from Bayer, which may not be available in all countries.

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

For more information, contact Bayer Customer Service. Please see back cover for contact information.

Error Detection Displays

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



- If there is an error (hardware, software, testing errors) detected by your meter, your meter will beep twice.
- You will see specific instructions to guide you. The first line of the error screen will tell you the error. The next lines describe what you should do. When an error screen displays an 0K, press the button next to it to continue.
- If you do not resolve the problem, contact Bayer Customer Service. Please see back cover for contact information.

Battery Status

Battery Status Displays

The battery status is 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 tell you that the battery is low and to Charge Soon.



If you do not charge the battery, a display alerts you: "Shutting down, Battery is dead." You must charge immediately.

Plug the meter into your wall charger or into the USB port of your computer. Be sure your computer is turned on and not in sleep, hibernate or power save mode.

The test strip port light flashes during charging and stops flashing and turns off 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 starts to charge immediately. While the battery charges, the test strip port light flashes slowly.

Press the top **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-powered USB port. When the battery is fully charged, the test strip port light turns off.

CAUTION: 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 to protect the meter from exposure to heat created by the computer.

NOTE: If the charging status displays "Low Power Charging," vour CONTOUR®NEXT LINK meter may be plugged into a low-powered USB port. Please try a different USB port on your computer. Only connect to a computer or a 5V charger approved by a certified body such as UL, TUV or CSA.



Battery Charging

AND CARE

Symptoms of High or Low Blood Sugar

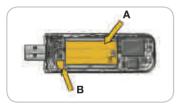
End of Meter Life/Battery Removal

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



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

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



Pry up rechargeable battery here (A). Disconnect battery by pulling battery connector (B).

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

Symptoms of High or Low Blood Sugar

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

Low blood sugar (Hypoglycaemia):	High blood sugar (Hyperglycaemia):	Ketones (Ketoacidosis):
 Shakiness Sweating Fast Heartbeat Blurred Vision Confusion Passing Out Irritability Seizure Extreme Hunger Dizziness 	 Frequent Urination Excessive Thirst Blurred Vision Increased Fatigue Hunger 	 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

Accuracy

The CONTOUR®NEXT LINK blood glucose monitoring system was tested in 100 capillary blood samples using 600 CONTOUR®NEXT test strips. Two replicates were tested with each of 3 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.8 The tables below compare the performance of the two methods.

Table 1 — System accuracy results for CONTOUR NEXT LINK meter using CONTOUR NEXT test strips at glucose concentration < 4.2 mmol/l

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
63/78	78/78	78/78
(80.8%)	(100%)	(100%)

Table 2 — System accuracy results for CONTOUR NEXT LINK meter using CONTOUR NEXT test strips at glucose concentration > 4.2 mmol/l

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
402/522	518/522	522/522	522/522
(77.0%)	(99.2%)	(100%)	(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 +/- 0.83 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 LINK blood glucose monitoring system using five venous whole blood specimens with glucose levels from 2.4 to 18.2 mmol/L. Multiple replicates (n=100 per lot) were tested using multiple CONTOUR NEXT LINK blood glucose meters and 3 lots of CONTOUR®NEXT test strips. The following precision results were obtained.

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

Mean Glucose Level, mmol/L	Standard Deviation, mmol/L	Coefficient of Variation (%)
2.41	0.05	2.1%
4.50	0.11	2.4%
6.78	0.08	1.2%
11.46	0.14	1.2%
18.34	0.35	1.9%

Principles of the Procedure

The CONTOUR NEXT LINK blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and a phenothiazine derivative as a 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.



AND CAR

Comparison Options

The CONTOUR®NEXT LINK system is designed for use with capillary whole blood. Comparison to a laboratory method must be done simultaneously with aliquots of the same sample. Note: Glucose concentrations drop rapidly due to glycolysis (approximately 5%-7% per hour).9

Important Information

This equipment has been tested and found to comply with the Industry Canada Standard in RSS-210. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

The term "IC:" before the certification/registration number only signifies that the Industry Canada technical specifications were met.

Operation is subject to the following two conditions:

- 1) this device may not cause interference, and
- 2) this device must accept any interference, including interference that may cause undesired operation of the device. If you have questions, please contact Bayer Customer Service. Please see back cover for contact information.

Service Information

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

Important

Speak to a Bayer Customer Service 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®NEXT LINK 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 nearby.

Check List

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

- Locate the model number (A) and serial number (B) on the back of the meter.
- 2. Locate the test strips' expiry date on the bottle.
- 3. Check the battery symbol on the screen. (See page 55, Battery Status.)



Symbols Used

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

Symbol	What It Means	Symbol	What It Means
\square	Use by date (last day of month)	0	Recycle Packaging
LOT	Batch code	CONT N	Control Range Normal
∩45°C	Temperature	CONT L	Control Range Low
5°C-∕	limitations	CONT H	Control Range High
Ţį	Consult instructions for use	2	Do not reuse
IVD	In Vitro Diagnostic Medical Device	STERILE R	Sterilized using irradiation
REF	Catalogue number	Ţ	Caution

	Symbol	What It Means
	X	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.
	Z	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 whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 uL

Measuring Range: 1.1 mmol/L to 33.3 mmol/L

Countdown Time: 5 seconds

Memory: Stores most recent 1.000 test results

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: 0°c $\int_{0}^{30^{\circ}C}$

Normal Control Storage Temperature Range: or 1

Humidity: 10%-93% RH

Dimensions: 97 mm wide x 31 mm high x 18 mm thick

Weight: 43 grams

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

Electromagnetic Compatibility (EMC): The CONTOUR®NEXT LINK 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 LINK 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 LINK 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 LINK meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

TECHNICAL AND CARE

Cleaning and Disinfection

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 well before handling to keep the meter and test strips free of water, oils, and other contaminants.
- Keep blood, control solution, and cleaning fluid from entering the test strip port or USB plug.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- The USB cap of your CONTOUR®NEXT LINK meter is designed to protect the USB plug. Should you lose the cap, contact Bayer Customer Service for a replacement. Please see back cover for contact information.

Cleaning and Disinfection

Your CONTOUR®NEXT LINK 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 LINK 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 LINK system should be cleaned of dirt and debris once a week.

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

! WARNING

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

NOTE: If the 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.

The cleaning and disinfecting directions provided will not cause any damage or degradation to the external case, buttons or display. Your CONTOUR®NEXT LINK meter and MICROLET®2 lancing device have been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). These devices have been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should call Bayer Diabetes Care Customer Service for assistance if your device malfunctions for any cause or if you notice any changes in the meter case or display.

For more information see:

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

http://www.fda.gov/Medical Devices/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/ahc-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.

66

TECHNICAL AND CARE

Cleaning and Disinfection





Buttons

USB Connector (under cap)

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 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.

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

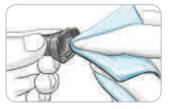
Supplies Needed for Disinfecting:

- 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.







References



- Use the germicidal wipes to disinfect all exposed surfaces of your lancing device until wet.
- 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 Customer Service to troubleshoot the issue and provide a solution. Please see back cover for contact information.

Warranty

Your MICROLET 2 lancing device is warranted for 5 years.

Supplies

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

Replacement Parts Items

- CONTOUR®NEXT LINK user guide
- CONTOUR NEXT LINK quick reference guide
- USB extension cable from Bayer
- USB cap
- Wall charger
- CONTOUR®NEXT test strips
- CONTOUR®NEXT control solution
- MICROLET®2 lancing device
- MICROLET® lancets
- Check the website www.bayerdiabetes.com for any meter updates or GLUCOFACTS®DELUXE updates.
- To order parts, contact Bayer Customer Service. Please see back cover for contact information.

References

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Manufacturer's Warranty

Bayer HealthCare 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 HealthCare 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:

- 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 HealthCare 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 HealthCare, or failure to operate the instrument in accordance with instructions. Further, Bayer HealthCare assumes no liability for malfunction or damage to Bayer HealthCare instruments caused by the use of reagents other than the appropriate reagents (e.g., CONTOUR®NEXT test strips) manufactured or recommended by Bayer HealthCare.
- 3. Bayer HealthCare reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
- 4. Bayer HealthCare has no knowledge of the performance of the CONTOUR®NEXT LINK blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore makes no warranty of the performance of the CONTOUR NEXT LINK meter when used with any test strips other than CONTOUR NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.

- 5. Bayer HealthCare makes no warranty of the performance of the CONTOUR®NEXT LINK meter or test results when used with any control solution other than CONTOUR®NEXT control solution.
- 6. Bayer HealthCare makes no warranty of the performance of the CONTOUR NEXT LINK meter or test results when used with any software other than GLUCOFACTS®DELUXE diabetes management software from Bayer (where supported) and CareLink® Personal therapy management software from Medtronic.

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

IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HEALTHCARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact Bayer Customer Service for assistance and/or instructions for obtaining service of this instrument. Please see back cover for contact information.



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