



Uses only CONTOUR®NEXT blood glucose test strips

**USER GUIDE** 

### **INTENDED USE**

The CONTOUR®NEXT 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 system is intended for the quantitative measurement of glucose (from 0.6 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 blood glucose monitoring system may also be used by health care professionals to monitor hypoglycemia in neonates. The system should not be used for diagnosis or screening. Diagnosis of neonatal hypoglycemia should be performed using a laboratory glucose method. For neonates exhibiting hypoglycemic symptoms, provide appropriate medical care to treat symptoms and monitor patients. If symptoms are inconsistent with meter results, obtain a laboratory blood glucose test. The CONTOUR NEXT blood glucose monitoring system has not been evaluated specifically with pre-term neonates.

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

The CONTOUR NEXT blood glucose monitoring system is intended for *in vitro* diagnostic use only.

The CONTOUR NEXT blood glucose monitoring system is intended for single-patient use only and should not be shared.

## **IMPORTANT SAFETY INFORMATION**

#### WARNINGS

## **Serious Illness**

• Capillary (fingerstick or Alternative Site) blood glucose testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples

Contour next of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.  $^{\rm 1-3}\,$ 

# Talk to Your Health Care Professional

- Before setting any Target ranges 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 and dry them well before and after testing, handling the meter, lancing device or test strips.
- The meter, lancing device and lancets provided with your kit are for single-patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- 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 22.
- The lancing device provided with your kit should not be used for assisted blood draws by health care professionals or at health care provision sites.
- Use a new 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.
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your poison control center.

# PRECAUTIONS

- Read your CONTOUR®NEXT meter user guide, the 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 Customer Service. See the back cover for contact information.
- The CONTOUR®NEXT 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, contact Customer Service. See the 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°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.
- Do not perform a blood glucose test when the CONTOUR®NEXT meter is connected to a computer.

- Use only approved equipment from the manufacturer or certified body such as UL or TUV.
- It is advisable to avoid use of electronic devices in very dry environments, especially if synthetic materials are present.
- Your CONTOUR®NEXT 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.



- \* Check your display screen to be sure the results are shown the right way. If not, contact Customer Service. See the back cover for contact information.
- The CONTOUR®NEXT blood glucose monitoring system has a measuring range of 0.6 mmol/L to 33.3 mmol/L.
  - \* For results over 33.3 mmol/L or under 0.6 mmol/L:
    - If your blood sugar reading is under 0.6 mmol/L, the "Result Under 0.6 mmol/L" screen will instruct you to "Follow Medical Advice Immediately." Contact your health care professional.
    - If your blood sugar reading is over 33.3 mmol/L the "Result Over 33.3 mmol/L" screen will instruct you to "Wash hands or test site. Repeat test with new strip". If results are still over 33.3 mmol/L, "Follow Medical Advice Immediately" is displayed.

#### **Your Meter Features**

**Easy:** The CONTOUR<sup>®</sup>NEXT blood glucose monitoring system is about simplicity. You will notice this the first time you use it.

Automatic: The CONTOUR®NEXT meter is designed with No Coding technology, to automatically code itself every time you insert a test strip. It will also automatically mark a control solution test.



**Enough Blood:** The CONTOUR NEXT meter alerts you when a test strip is under-filled and allows you to add more blood. Your test strip is designed to easily "sip" the blood into the sample tip. Do not drop blood directly on the flat surface of the test strip.

Thank you for choosing the CONTOUR NEXT blood glucose monitoring system. We are proud to be your partner in helping you manage your diabetes.

**CAUTION:** Your CONTOUR®NEXT meter ONLY works with CONTOUR®NEXT test strips and CONTOUR®NEXT control solution.



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**TECHNICAL** INFORMATION

FEATURES

GETTING STARTED

TESTING

# **GETTING STARTED**

Your CONTOUR®NEXT Metel

# Your CONTOUR®NEXT Meter



#### **OK Button** Press and hold to turn the meter On or Off

Press to accept a highlighted selection

## **Using the Meter Buttons**

Up/Down

Press to scroll up

Press and hold

Press to

scroll down

Press and hold

to keep scrolling

to keep scrolling

- Press and hold the OK button until the meter turns on.
- Press and hold the OK button until the meter turns off.
- The ▲ or ▼ scroll buttons on the meter allow you to scroll through the menus. You can hold the  $\blacktriangle$  or  $\blacktriangledown$  button to scroll continuously through a list.
- Press the **OK** button to select the highlighted option.
- To exit from the Logbook or Trends and return to the Main Menu, press the **OK** button.
- To exit from Setup and return to the Main Menu, scroll down to Main Menu and press the OK button.



Listed below are symbols that appear on the CONTOUR®NEXT meter screen. These symbols will appear in the left side of the screen, as shown here:

<ul> <li>✓ Languag</li> <li>English</li> <li>✓ OK</li> <li>X No</li> </ul>	e: Example of Language confirmation screen
Symbol	What it Means
	When you select More Information.
	On confirmation screens and when blood sugar test result is in Target range.
8	On error screens and when blood sugar test result is either below 0.6 mmol/L or above 33.3 mmol/L.
Đ	When blood sugar test result is above Target.
Ŧ	When blood sugar test result is below Target.

3

GETTING STARTED

Contour lext

# GETTING STARTED

# Your CONTOUR®NEXT Test Strip



Sample Tip Blood sample pulled in here **Initial Setup** 

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

#### LENGURGE ✓ English Français Español Português Italiano

 Press the ▼ button if needed to select your desired language. Press the ▼ button to scroll down to see more language choices.

This screen example shows the language selections. The language order may differ depending on your country.

3. When your language is highlighted, press the **OK** button.



5. Press the OK button to complete setup. Your meter is now ready to test your blood sugar.

You can also change your language, time and date by going to the Main Menu and selecting Setup. See page 39.

# **Getting Ready to Test**

**i** Read your CONTOUR®NEXT meter user guide, the 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 Customer Service for replacement parts. See the back cover for contact information.

**CAUTION:** Your CONTOUR®NEXT 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 meter, CONTOUR NEXT test strips, and the lancing device and lancets. You may also need CONTOUR NEXT control solution to perform a quality control check. CONTOUR NEXT test strips and CONTOUR NEXT control solutions are sold separately if not included in the meter kit.

#### WARNING

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

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

#### Preparing the Lancing Device

The lancing device graphics are for illustration purposes only. Your lancing device may look different. Refer to your lancing device insert for detailed instructions on preparing the lancing device.

For Alternative Site Testing instructions, see page 16.

#### **WARNING: Potential Biohazard**

The lancing device provided with your kit is intended for single patient use only. The lancing 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 lancet each time you test because it is no longer sterile after use.

1. Remove the endcap from the lancing device.



2. Loosen the round protective cap on a lancet by rotating it ¼ turn, but do not remove it.



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



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



5. Replace the endcap.



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

### **Inserting the Test Strip**

1. 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 toward the meter.

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**3.** 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 the test strip is inserted, if you do not apply blood to the test strip within 3 minutes, the meter will turn off. Remove the test strip and reinsert it to begin a test.

# resting

Preparing the Lancing Device



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TESTING

# Getting the Blood Drop – Fingertip Testing





- 1. Press the lancing device firmly against the puncture site and press the release button.
- 2. Stroke your hand and finger toward 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 as shown.
- **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 because this could lead to inaccurate results or errors.

# Apply More Blood



If the first blood drop is not enough, the meter will beep twice and display "**Apply More Blood to continue testing**." You have about 30 seconds to apply more blood to the same strip.



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 start with a new strip.

**TESTING** 

Getting the Blood Drop – Fingertip Testing

## AutoLog

TESTING

AutoLog

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

**No Mark** - No Mark can be selected if you are testing at other times than before or after a meal or fasting.

C Fasting – Use the Fasting marker when testing blood sugar levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).

**Before Meal** - The Before Meal marker is used when testing blood sugar levels within 1 hour before a meal.

**ffter Meal** – The After Meal marker is used when testing blood sugar levels within 2 hours after the first bite of a meal.

Your meter comes with AutoLog turned on. You will get the most information from each result if you keep this feature turned on.

AUTOLOG	ľ
Testing	l
No Mark	
O Fasting	
🗂 Before Meal	
🗯 After Meal	

# **Test Results**

# Test Results with AutoLog On

• Your CONTOUR<sup>®</sup>NEXT meter comes with AutoLog on. You can turn AutoLog off using the Setup menu (see page 45).

AUTOLOG	J
Select Mark	
No Mark	
O Fasting	
💼 Before Meal	
🛱 After Meal	

After you place blood on the test strip, your test result will not display until you make an AutoLog selection. Use the ▲ or ▼ button to select No Mark, Fasting, Before Meal, or After Meal, and then press the OK button.

If your result is outside your Target range setting, you will see your result without pushing a button.



To get the most from your AutoLog feature, mark your test result right away. If you make your AutoLog selection very quickly, you may see the remainder of the testing countdown.

If you have not made your AutoLog selection within 1 minute, the screen will dim. Press any button to turn the screen back on and make your choice. If you have not made your choice within 3 minutes, the meter turns off. Your blood sugar result will not be lost — it will be stored in Logbook as No Mark.

**CAUTION:** If your result is above or below your set Target ranges, you will always see your result without pushing a button.



TESTING

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**Test Results with AutoLog** 

After making your selection, your test result appears. Press the **OK** button to move to **See Options**.

HINT: The screen above shows a result that is within the Target Range you set for an After Meal result. The screens below show an After Meal result that is Below Target and an After Meal result that is Above Target.



or nons	
Main Menu	
Add Note	
Add Reminder	

Leave the test strip in the meter to add a note related to this result or set a reminder. Press the **OK** button and you can select **Main Menu**, **Add Reminder** (see page 30) or **Add Note** (see page 34).

To turn the meter off if you do not want to set a reminder or add a note, remove the test strip.

### Test Results with AutoLog Off



After applying blood to the test strip when AutoLog is Off, your result will appear. You may see the 5 second countdown screen.



Your test result appears. Press the **OK** button to move to **See Options**.



#### OPTIONS



Leave the test strip in the meter to add a note related to this result or set a reminder. Press the **OK** button and you can select **Main Menu**, **Add Reminder** (see page 30) or **Add Note** (see page 34).

To turn the meter off if you do not want to set a reminder or add a note, remove the test strip.

# 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 on your lancing device if provided with your kit. Your CONTOUR®NEXT meter can be used for fingertip or palm testing. See the lancing device 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 endcap to perform AST, contact Customer Service. See the back cover for contact information.

# 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 lancing device if provided with your kit. Refer to the lancing device insert for detailed instructions.
- **3.** Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones and tendons.

The lancing device graphics are for illustration purposes only.

4. Press the lancing device firmly against puncture site and then press the release button.

**TESTING** 

- Palm

Alternative Site Testing (AST)



- **5.** Maintain steady pressure until a small, round blood drop forms.
- Non-
- 6. Lift the device straight up and away from the skin without smearing the blood.



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

Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip. Do not test the blood sample from palm if you get:

- Smeared blood
- Clotted blood

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



If the first blood drop is not enough, the meter will beep twice and display "Apply More Blood to continue testing." You have about 30 seconds to apply more blood to the same strip.

9		(	EO
<b>Too Li</b> i Remove Repeat strip.	<b>ttle</b> e use test	<b>Bloo</b> d stri with	<b>d</b> ip. ne

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

**CAUTION:** If your result is above or below your set Target ranges, you will always see your result without pushing a button.

Please see Test Results with AutoLog On, page 13, or Test Results with AutoLog Off, page 15.

**TESTING** 

TESTING

Getting a Blood Drop for Alternative Site Testing

**Caring for Your Mete** 

#### **Ejecting and Disposing of the Used Lancet**



- Do not use your fingers to remove the lancet from the lancing device. The lancing device provided with your kit has an automatic lancet ejection feature.
- 2. Refer to the separate lancing device insert provided with your kit for instructions on automatic ejection of the lancet.

#### WARNING

- Dispose of the used lancet as medical waste or as advised by your health care professional.
- Do not reuse lancets. Use a new 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.
- Always dispose of the used 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.

#### **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.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.

#### **Cleaning and Disinfection**

Your CONTOUR®NEXT meter 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 meter.

#### Refer to the lancing device insert provided with your kit for detailed instructions for cleaning and disinfecting the 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 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 and dry them well before and after testing, 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. Health care professionals should follow their institution's policy on the frequency of disinfection.

The cleaning and disinfecting directions provided will not cause any damage or degradation to the external case, buttons or display. Your CONTOUR NEXT meter has been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should contact 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:

US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010.

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

## **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.



**TESTING** 

**Cleaning and Disinfection** 

#### **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 and Disinfecting Your Lancing Device**

Refer to the lancing device insert provided with your kit for detailed instructions for cleaning and disinfecting the lancing device.

TESTING

# **Expected Test Result 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 mmol/L – 6.1 mmol/L in the fasting state.<sup>4</sup>

#### WARNING

You should consult with 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, call your health care professional as soon as possible.
- Always consult your health care professional before changing your medication based on test results.

# **Control Solution Testing**



Shake the control solution well before testing.



*TESTING* 

Expected Test Result Values

**CAUTION:** Use only CONTOUR®NEXT control solutions (Normal, Low and High) with your CONTOUR®NEXT blood glucose monitoring system. Using any other control solution or any other combination of control solution and strips can cause inaccurate results.

# **Quality Control**



- Shake the control solution bottle well, about 15 times before every use.
- Unmixed control solution may cause inaccurate results.

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 properly.
- You have repeated, unexpected blood glucose results.

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- 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 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 and sold separately if not included in the meter kit. You can test your CONTOUR®NEXT meter with control solution when the temperature is 15°C–35°C. Always use CONTOUR®NEXT control solutions. Other brands could present incorrect results. If you need help locating CONTOUR NEXT control solutions, contact Customer Service. See the back cover for contact information.

**Control Solution Testing** 

- 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 up.



**3.** Insert the grey square end of the test strip into the test strip port until the meter beeps.

Apply Blood



4. The meter will turn on and show a test strip with a flashing blood drop.



- Shake the control solution bottle well, about 15 times before every use.
- **6.** Remove the 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 solution onto a clean nonabsorbent surface.

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

**8.** Immediately touch the tip of the test strip to the drop of control solution.



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next

9. Hold the tip in the drop until the meter beeps.

12/05/12 10:20 PM CONTROL TEST mmol/L Main Menu



5 seconds and the control test result will display on the meter. It will be automatically marked as a control test and stored in the Logbook. Control test results will not be included in your blood sugar averages.

10. The meter will count down for



- **11.** Compare your control test result with the range printed on the test strip bottle or the bottom of the test strip box.
- **12.** Remove the test strip and dispose as medical waste.

**CAUTION:** If the result you get does not fall within the range listed on the test strip bottle label or carton, there may be a problem with the test strips, the meter or your testing technique.

If your control test result is out of range, do not use your CONTOUR®NEXT meter for blood glucose testing until you resolve the issue. Contact Customer Service. See the back cover for contact information.

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**TESTING** 

# **Test Reminders**

A reminder for your next test can be set after testing or from the Setup menu. See page 40 for Setting a Reminder from the Setup Menu.

## Setting a Reminder After Testing



1. With the test strip still in the meter, press the OK button when See Options is highlighted.

OPTIONS
Main Menu
Add Note
Add Reminder

- 2. Press the ▼ button to select Add Reminder.
- 3. Press the OK button to start the countdown. The default time is either 2 hours or the last reminder time that was set.

<b>Countdown:</b> 2 hrs	
Start	
Change	
Go Back	

DEMINDED

You can change the Reminder Countdown time to the time you wish by selecting Change. Then press the **OK** button.

# **Turning Off a Reminder After Testing**

1. Press the **OK** button and if the Countdown is currently on, the screen will show Reminder in.

9 REMINDER
Reminder in: 30 mins
Stop
Change
Go Back

2. To stop the Countdown, select \$top. Press the **OK** button.

A screen confirms your choice.

The Countdown is now stopped and the clock symbol will no longer appear on the screen.

# **Changing the Reminder Time**



- **1.** Press the  $\blacktriangle$  or  $\checkmark$  button to select the correct hours. Press the **OK** button to continue.



- **2.** Press the  $\blacktriangle$  or  $\checkmark$  button to select the minutes (in 15 minute increments).
- 3. Press the **OK** button to continue.

Continue

FEATURES

D OPTIONS Main Menu

Add Note

Change Reminder

 $\checkmark$ Reminder in:

2 hrs 30 mins

A screen confirms the **Reminder** Countdown time.

#### When the **Reminder** feature is on, the clock symbol is in the header area of many of the menu screens.

Remove the test strip from the meter. The meter retains the Reminder time that you set until you change it.

#### **Getting a Reminder**

)	When the Reminder time is reached,
ne for your next	20 beeps will sound. The meter will
st.	turn on and a Reminder screen will
	appear. You can stop the beeps by
	pressing the <b>OK</b> button or inserting
ntinue	a test strip.

HINT: If you are testing within 15 minutes of the Reminder, the Reminder will be cancelled.

# Logbook

## **Reviewing the Logbook**

The Logbook contains blood sugar test results and notes that you have made to those test results. The Logbook will hold up to 800 results. When the maximum is reached, the oldest test result will be removed as a new test is completed and saved to the Logbook.

To review these entries in the Logbook:

	12:35	ЯM
Logbook		
Trends		
Setup		

- 1. Press and hold the **OK** button until the meter turns on.
- 2. Press the OK button again to select Logbook from the Main Menu.



End of Logbook

Back to Beginning

Previous Screen

Main Menu

LOGBOOK

- **3.** Press the ▼ button to view your individual test results.
- 4. Scroll through your test results by pressing the  $\blacktriangle$  or  $\checkmark$  button.

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

5. Press the OK button to go to Back to Beginning to review entries. Use the ▼ button to select Previous Screen

or Main Menu and then press the OK button.

Reminder

FEATURES

FEATURES

Logbook

# Notes

OPTIONS

FEATURES

Notes

### Adding a Note

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 **OK** button when **See Options** is highlighted.

Main Menu	
Add Note	
Add Reminder	
l j	

 Press the ▼ button to select **Add Note**. If you have marked your test result using AutoLog, that entry will have a check in front of it.

ĺ	NOTES	
	After Meal	
	Time After Meal	
	Don't Feel Right	
	Sick	
ļ	Stress	_

 Press the ▼ or ▲ button to scroll through the choices. Some may not be visible until you scroll up or down. Press the OK button when your choice is highlighted. A screen confirms your choice. All options may not be available based on the meal marker you choose.

HINT: You can remove a Note that you just added. Highlight the Note and press the OK button. Once you return to the Main Menu, you cannot remove a Note or change a Note.

# Trends (Averages and Summaries)

The Trends feature displays your average and a summary of your test\_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. You can review your 14-day Fasting, Before Meal, and After Meal Summaries and Averages. Your 90-day average is not intended to be reflective of your HbA1c result.

# Viewing Trends with AutoLog On

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



You will see your 14-day **Fasting Average** first. This example shows that your average of 13 readings is 5.2 mmol/L.



3. Press the ▼ button to see your 14-day Fasting Summary. This example shows 1 test result Above Target, 10 test results In Range and 2 test results Below Target. In this example the Target Range is 3.9 - 7.2 mmol/L for the 14 days.

HINT: From any screen while viewing the Trends, press the OK button on your meter to return to the Main Menu.





✓ 20 In Range

♣ 2 Below Target

TRRGET: 3.9 - 7.2

Before Meal

Average (14 Day)

6.5<sup>mmol/L</sup>

 Continue to press the ▼ button to see your 14-day Before Meal Average.

5. Press the ▼ button to see your 14-day Before Meal Summary. This example shows 3 test results Rbove Target, 20 test results In Range and 2 test results Below Target. In this example the Target Range is 3.9 - 7.2 mmol/L for the 14 days.



- Continue to press the ▼ button to see your 14-day After Meal Average. This example shows your average of 23 readings is 8.2 mmol/L.
- Image: Summary (14 Day)

   Summary (14 Day)

   Image: Summary 3 Above Target

   Image: Summary 10 In Range

   Image
- 7. Press the ▼ button to see your 14-day After Meal Summary. This example shows 3 <u>test results</u> **fibove** Iarget, 19 <u>test results</u> In Range and 1 <u>test result</u> Below Iarget. In this example the Iarget Range is 3.9 - 10.0 mmol/L for the 14 days.

Overall Average (14 Day) 6\_6<sup>mmol/L</sup> Readings: 58



 Continue to press the ▼ button to see your Overall 14-day Average. This example includes ALL your results for 14 days and shows an overall average for 58 readings of 6.6 mmol/L.



# **Changing the Trends Time Period**



Other trend time periods are available through the See More Trends menu. You will see the See More Trends menu after the Overall Average screen. Scroll through your Trends using the ▼ button on your meter.

TRENDS

7–Day Trends 14–Day Trends 30–Day Trends 90–Day Trends Main Menu

- 1. Select See More Trends and press the OK button.
- 2. You can select the time period by highlighting your choice and pressing the **OK** button.

## Viewing Trends with AutoLog Off

If you have AutoLog turned off, you will only see trends for your overall Target.

- **1.** Turn on the meter by pressing and holding the **OK** button.
- 2. Press the V button to select Irends and then press the OK button.



You will see your 14-day Overall Average first.

🖬 Overall 🔒		
Summary (14 Day)		
🕈 3 Above Target		
✔40 In Range		
🗣 🏾 5 Below Target		
TARGET: <b>3.9 - 7.2</b>	-	

3. Press the ▼ button to view your Overall Summary. You will see your 14-day Overall Summary. This example shows 3 test results Above Target, 40 test results In Range and 5 test results Below Target. In this example the Target Range is 3.9 - 7.2 mmol/L for the 14 days.



**4.** Use the  $\mathbf{\nabla}$  or  $\mathbf{A}$  button to highlight See More Trends or Main Menu and press OK.

# Setup

#### In Setup you can:

Turn a Reminder on or off or Set a Reminder, Change the Date, Change the Time, Set Sound on or off, Turn AutoLog on or off, view or set Target ranges, Change the Language, Change the Display Background or Enter the Customer Service Mode.

#### To get to the Setup Menu:



1. Press and hold the OK button until the meter turns on.

#### 12:35 AM

Logbook Trends Setup

The Main Menu has 3 choices: Logbook,

- 2. Press the ▼ button to highlight Setup.
- 3. Press the OK button.

Irends and Setup.

FEATURES

FEATURES

#### Setting a Reminder

SETUP	
ŕ	
Reminder: Off	
Date	
Time	
Sound	
AutoLog -	

- 1. Press and hold the OK button until the meter turns on.
- 2. On the Setup Menu, you will see a list of options with the Reminder option highlighted.

SETUP	
Display	
Customer Service	
Main Menu	

3. To change a Reminder, press the OK button and follow steps on page 31 "Changing the Reminder Time." To leave the Reminder option as it is set, press the ▼ button to go back to Main Menu.

# **Turning Off a Reminder**

🕒 REMINDER	1. Go to the Main M
Reminder in:	and press the Ok
1 nr 45 mins	2. With Reminder: Or
Stop	OK button.
Change	3. Select Stop and p
Co Pack	

- /lenu. Select Setup K button.
- n selected, press the
- press the **OK** button.
- 4. The Countdown is now stopped.

Reminder is stopped. A screen confirms your choice.

# Date

# DATE mm/dd/yy 8/23/12

Change Go Back

#### DATE

# Select Date Format: 8/23/12 Month/Day/Year

Day.Month.Year

8/23/12

#### DATE Change Year:

5. Change year (highlighted) by using the ▲ or ▼ button. Press the

▲ or ▼ button. Press the **OK** button.

1. Press and hold the OK button until

2. From the Setup Menu, use the ▼

button to highlight the Date. Press the

3. Change will be highlighted. Press the

the meter turns on.

4. Select Month/Day/Year or

Day.Month.Year by using the

OK button.

**OK** button.

OK button.

Continue

- DATE Change Month:

8/23/12

6. Change month (highlighted) by using the  $\blacktriangle$  or  $\blacktriangledown$  button. Press the OK button.

Continue

FEATURES

FEATURES

 $\checkmark$ 



7. Change day (highlighted) by using the ▲ or ▼ button. Press the **OK** button.



#### 8. A screen confirms your date setting. Done will be highlighted. Press the OK button.

# Time

FEATURES

**Date and Time** 

	_
SETUP	
	^
Reminder: Off	
Date	Г
Time: 1:03 PM	
Sound	
AutoLog	

- 1. Press and hold the OK button until the meter turns on.
- 2. From the Setup Menu, use the V button to highlight the Time. Press the **OK** button.

- - 3. Change will be highlighted. Press the **OK** button.

#### IIME

#### Select Time Format:

1:03 PM

#### 12-hour clock 24-hour clock



5. Change the hour (highlighted) by using the  $\blacktriangle$  or  $\blacktriangledown$  button. Press the OK button.

4. Change the time format if needed.

Press the **OK** button.

# IME Change minutes: 2:05 PM

Continue

Continue

- 6. Change minutes (highlighted) by using the  $\blacktriangle$  or  $\blacktriangledown$  button. Press the OK button.



7. When in 12-hour clock mode, select AM or PM and press the OK button. Time



8. Done will be highlighted. Press the **OK** button.

#### Sound

Your meter comes with the Sound turned on. Certain error messages and the Reminder bell override any Sound setting. One long beep indicates a confirmation when Sound is On. Two beeps indicates an error or something that needs your attention when Sound is On.

FEATURES

Sound

- 1. Press and hold the **OK** button until the meter turns on.
- 2. From the Setup Menu, select Sound and press the OK button to turn sound on or off. Press the OK button again to change the setting. A screen will confirm your choice.

 200110
Sound is On.
Turn Off
Go Back

To turn off the Sound, select Iurn Off. To keep the Sound on, select Go Back. The Setup menu appears upon completion. Some sounds stay on, even with the Sound turned off.

# AutoLog

Your meter comes with AutoLog turned On.

# **AutoLog Settings**

#### SETUP Time Sound AutoLoa: On Targets Language

- 1. Press and hold the **OK** button until the meter turns on.
- 2. From the Setup menu, choose **AutoLog** and press the **OK** button.
- AUTOLOG AutoLog is On. Accept Turn Off More Information
- CONFIRM TARGET 5. A screen then shows the current Target settings. Press the **OK** button
- Overall:

3.9 - 10.0 mmol/L

#### Accept Change

- 3. Make one of the following selections: Accept, Turn Off (Turn On), or More information.
- 4. If you select Accept or Turn (0n/Off), a screen is shown confirming that AutoLog is on or AutoLog is off.

to Accept these Target ranges.

section on the following page.

To change the Target range, highlight

To set Targets, see the Target setup

Change and press the OK button.

FEATURES

#### **Blood Sugar Target Ranges**

Your CONTOUR®NEXT meter comes preset with blood sugar Target ranges for Fasting, Before Meal, and After Meal results. The preset range is 3.9 - 7.2 mmol/L for Fasting and Before Meal, and 3.9 - 10.0 mmol/L for After Meal. These Target ranges are only available when AutoLog is ON. If AutoLog is OFF, you will have an Overall Target range only, which is preset to 3.9 - 10.0 mmol/L.

#### WARNING

Discuss your Target range settings with your health care professional.

# Setting Targets When AutoLog is ON

TARGETS	1
Target ranges are your blood sugar goals.	2
Set Targets	З
More Information	

FEATURES

**Blood Sugar Target Ranges** 

- 1. Press and hold the **OK** button until the meter turns on.
- 2. From the setup menu, select Targets. Press the **OK** button.
- **3.** Set Targets will be highlighted. Press the **OK** button.
- TARGETS **Fasting:** 3.9 - 7.2 mmol/L Accept Change
- The Fasting Target range will appear (3.9 – 7.2 mmol/L). You can ficcept the target by pressing the OK button.

#### ARGETS

○ Fasting: 3.9 - 7.2 mmol/L

#### Accept Change





# 6. Use the ▲ or ▼ button to change the highlighted value. When you see the value you want, press the OK button, and you will move to the next Fasting Target value (7.2 mmol/L)



 To change this Fasting Target value, use the ▲ or ▼ button and press the OK button when you are finished.

- ✓ Target set: ○ Fasting: 3.9 - 7.2 mmol/L
  - 8. Press the **OK** button to move to the Before Meal target.

Done Change

#### TARGETS

Accept Change

Before Meal: 3.9 - 7.2 mmol/L 9. The Before Meal Target range will appear (3.9 – 7.2 mmol/L). You can Accept the Targets by pressing the OK button.

TARGETS
<b>6 Before Meal:</b> 3.9 - 7.2 mmol/L
Accept
Change



TARGETS

 Use the ▲ or ▼ button to change the highlighted Before Meal Target value. When you see the Target value you want, press the OK button, and you will move to the next Target value.

**10.** To change the Target, press the ▼

button to highlight Change and

press the **OK** button.



12. To change the Target, use the ▲ or
 ▼ button and press the OK button when you are finished.



**13.** Press the **OK** button to move to the After Meal Target.

#### TARGETS

**# After Meal:** 3.9 - 10.0 mmol/L

#### Accept Change



# **14.** The After Meal Target range will appear (3.9 – 10.0 mmol/L). You can **ficcept** the highlighted Target by pressing the **OK** button.

- 15. To change the After Meal Target, press the ▼ button to select Change and press the OK button.
- Use the ▲ or ▼ button to change the Target value. When you see the Target value you want, press the OK button, and you will move to the next Target value. Press the OK button when you are finished.



- 17. Press the **OK** button to see all Targets.
- ✓ Targets: ○ 3.9 - 7.2 mmol/L 1 3.9 - 7.2 mmol/L 1 3.9 - 10.0 mmol/L

Done

Change

 A screen confirms that Targets are set. Done will be highlighted. Press the OK button.

To go back to Change the Targets, press the  $\mathbf{\nabla}$  button to highlight **Change** and then press the **OK** button. This will bring you back to the Fasting screen.

FEATURES

#### Setting Targets When AutoLog is OFF

SETUP			
Sound			
AutoLog			
Targets			
Language			
Display			

# TARGETS

Target ranges are your blood sugar goals.

Set Targets More Information

# TARGETS

Change

- Overall:
   3.9 10.0 mmol/L

  Accept
- 4. The Overall Target screen will appear. You can ficcept the preset Target range by pressing the OK button.

1. Press and hold the **OK** button until

2. From the Setup Menu, select Targets.

3. Set Targets will be highlighted. Press

the meter turns on.

Press the **OK** button.

the OK button.

#### TARGETS

**Overall:** 3.9 – 10.0 mmol/L

#### Accept Change



# ☑ Target set: Ħ Overall:

4.1 - 10.0 mmol/L

- 5. To change the preset Target, use the ▼ button to highlight Change and press the OK button.
- 6. If you select Change, press the ▲ or ▼ button until you see the Target value you want. Press the OK button to move to the next Target value and use the ▲ or ▼ button to change the Target. Press the OK button to Continue.
- 7. A screen will confirm that your Overall Target range is set. **Done** will be highlighted. Press the **OK** button.

To go back to Change the Targets, press the ▼ button to highlight **Change** and press the **OK** button. This will bring you back to the Overall Target range screen shown above.

Done

Change

#### Language

Logbook Trends Setup SETUP AutoLog Targets Language Display Customer Service		12:35 AM
Logbook Trends Setup AutoLog Targets Language Display Customer Service		
Trends Setup SETUP AutoLog Targets Language Display Customer Service	Logbook	
Setup <u>setup</u> AutoLog Targets Language Display Customer Service	Trends	
SETUP AutoLog Targets Language Display Customer Service	Setup	
SETUP AutoLog Targets Language Display Customer Service		
SETUP AutoLog Targets Language Display Customer Service		
SETUP AutoLog Targets Language Display Customer Service		
AutoLog Targets Language Display Customer Service	SETUP	
AutoLog Targets Language Display Customer Service		1
Targets Language Display Customer Service	AutoLog	
Language Display Customer Service	Targets	
Display Customer Service	Language	
Customer Service	Display	
	Customer S	Service 🔒
LANGUAGE	LANGUAGE	

✓ English

Français

Español

Italiano

Portuquês

1. Press and hold the **OK** button until the meter turns on.

- 2. From the Setup Menu, scroll down to Language and press the OK button.
- Press the ▲ or ▼ button to highlight your choice. Press the ▼ button to see more choices. Press the OK button.

This screen example shows the language selections. The language order may differ depending on your country.

- ✓ Language:
   English
   ✓ OK
   X No
  - 4. Press the **OK** button to confirm your choice.

The Setup Menu will appear in the language you selected.

# **Display Background**

You can change the Display to show black background with white text, or white background with black text.

#### setup Targets Language Display Customer Service Main Menu

- 1. Press and hold the **OK** button until the meter turns on.
- 2. From the Setup menu, scroll down to **Display** and press the **OK** button.



Display is white text on a black background.

#### Change Go Back



- 3. To change the display, select Change and press the OK button. To keep the current setting, select Go Back and press the OK button.
- Your new display background will show. A screen will confirm your choice.

The Setup menu will appear with your choice.

FEATURES

-anguage

# Customer Service (on the Setup Menu)

This option is needed only if you are speaking to a Customer Service representative. It is not for use at any other time. The Customer Service representative will give you a code to use to verify certain settings.

# **Caring for Your Meter**

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands 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.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust or dirt.
- Your meter should be cleaned and disinfected once a week. For cleaning and disinfection instructions, see pages 22-25.

# Transferring Results to a Computer

You can transfer test results from the CONTOUR®NEXT meter to a computer, where they can be summarized in a report with graphs and tables. To make use of this feature, you need GLUCOFACTS®DELUXE diabetes management software and a 1-meter (or 3-foot) long USB-A to MicroUSB-B cable. This type of cable is available in electronics retail stores. For a free download of the software go to **www.glucofacts.ascensia.com** or contact Customer Service. See the back cover for contact information.

#### **IMPORTANT:**

- The CONTOUR NEXT meter has not been tested or certified for use with any software other than GLUCOFACTS DELUXE diabetes management software. Ascensia Diabetes Care is not responsible for any erroneous results from the use of other software.
- You cannot perform a blood sugar test when the CONTOUR NEXT meter is connected to a computer.

# **Batteries**

Continue

now. c

**Dead Batteries** 

**Replace batteries** 



842

When the batteries are low, the Low Batteries screen displays. Press the OK button to acknowledge the warning. The system continues to operate normally, but the low batteries icon appears on the Main menu until the batteries are replaced. Change the batteries right away. You may only test about 10 more times over the next three days before the batteries run out.

When you are no longer able to perform a test due to low batteries, the **Dead Batteries** screen will show. Change the batteries immediately.

# HELP

HELP

Customer Service (on the Setup Menu)

#### **Changing the Batteries**



Turn off your meter before changing your batteries. Press firmly on the battery cover and slide in the direction of the arrow.

HINT: If you put the new batteries in the meter within 5 minutes of taking the old ones out, all your settings and results will be saved. If you take more than 5 minutes to change the batteries, check the date and time to ensure they are still correct. Other settings and results will be saved.

Remove both of the old batteries. Replace with two 3-volt lithium batteries (DL2032 or CR2032).



Place new batteries into the battery compartment with the "+" side up. Slide the battery cover back into place.

Discard batteries according to your local environmental regulations.

#### WARNING

Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your physician or poison control center.

# **Error Detection Displays**

The meter display screen provides information for test result, strip, or system errors.

If there is an error the meter will beep 2 times. Follow the on-screen instructions. Press the **OK** button if needed.

If you experience continued errors, contact Customer Service. See the back cover for contact information.

# For Result Above 33.3 mmol/L or Below 0.6 mmol/L



Continue

- If your blood sugar reading is under 0.6 mmol/L, the "Follow Medical Advice Immediately" screen will display and the meter will beep twice. Contact your health care professional.
- (E22) Result Over 33.3 mmol/L Wash hands or test site. Repeat test with new strip. Continue
- If your blood sugar reading is over 33.3 mmol/L, the next screen will tell you to retest. The meter will beep twice. Wash and dry your hands well and retest with a new strip.
- If results are still over 33.3 mmol/L, "Follow Medical Advice Immediately" is displayed.

**Changing the Batteries** 

HELP

## Strip Errors



A strip error displays if a used strip is inserted, the strip is inserted upside down, or the wrong strip is inserted.

## **Testing Condition Errors**



A testing condition error displays when the meter is too cold or too hot to test.

(F64)

#### **System Errors**



Strip Errors

(E80)  $\mathbf{T}$ Software Error Hardware Error Turn off, then on. Turn off, then on. If error persists, call If error persists, call Customer Service/ Customer Service/ Support. Support.

A system error displays when either the meter software or hardware malfunctions.

# System Support Information

Speak to a Customer Service Representative before returning your meter for any reason. See the back cover for contact information.

#### Checklist

When speaking with Customer Service:



Have your CONTOUR®NEXT blood glucose meter, CONTOUR®NEXT test strips. and CONTOUR®NEXT control solution available when you phone.

Locate the model number (A) and serial number (B) on the back of the meter.

Locate the test strips' expiration date on the bottle. Check the battery status.

#### Parts Information

To replace missing parts or reorder supplies, contact Customer Service. See the back cover for contact information.

Two 3-volt Lithium Batteries DL2032 or CR2032 CONTOUR®NEXT User Guide CONTOUR®NEXT Quick Reference Guide CONTOUR®NEXT Test Strips CONTOUR®NEXT Normal Control Solution CONTOUR®NEXT I ow Control Solution CONTOUR®NEXT High Control Solution Lancing Device I ancets

#### Technical Information Accuracy

The CONTOUR®NEXT 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. The tables below compare the performance of the 2 methods.

# Table 1 – System accuracy results for glucose concentration < 5.55 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	167 of 180 (92.8%)	179 of 180 (99.4%)	180 of 180 (100%)

# Table 2 – System accuracy results for glucose concentration $\geq 5.55~\text{mmol/L}$

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	319 of 420 (76.0%)	412 of 420 (98.1%)	419 of 420 (99.8%)

# Table 3 – System accuracy results for glucose concentrations between 1.3 mmol/L and 30.6 mmol/L

Within  $\pm$  0.83 mmol/L or  $\pm$ 15%

599 of 600 (99.8%)

Acceptance criteria in ISO 15197: 2013 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within  $\pm 0.83$  mmol/L for glucose values less than 5.55 mmol/L, and within  $\pm 15\%$  for glucose values greater than or equal to 5.55 mmol/L.



#### User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 221 lay persons showed the following results: 100% within  $\pm$  0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.9% within  $\pm$  15% of the medical laboratory glucose concentrations at or above 5.55 mmol/L.

#### Precision

A repeatability study was conducted with the CONTOUR®NEXT blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 to 17.9 mmol/L. Multiple replicates (n=300) were tested using multiple CONTOUR NEXT blood glucose meters and 3 lots of CONTOUR®NEXT blood glucose test strips. The following precision results were obtained.

# Table 4 – System repeatability results for CONTOUR NEXT meter using CONTOUR NEXT test strips

Mean, mmol/L	Pooled Standard Deviation	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
2.2	0.05	0.043 – 0.051	2.1
4.8	0.07	0.062 - 0.073	1.4
6.8	0.09	0.082 - 0.097	1.3
11.4	0.15	0.138 – 0.164	1.3
18.2	0.26	0.238 - 0.282	1.4

Intermediate precision (which includes variability across multiple days) was evaluated using 3 control solutions. With each of 3 lots of CONTOUR NEXT Test Strips, each control was tested once on each of 10 instruments on 10 separate days for a total of 300 readings.

# Table 5 – System intermediate precision results for CONTOUR NEXT meter using CONTOUR NEXT test strips

Control Level	Mean, mmol/L	Standard Deviation, mmol/L	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
Low	2.41	0.04	0.036 - 0.043	1.6
Normal	7.16	0.10	0.093 – 0.111	1.4
High	21.30	0.35	0.321 – 0.380	1.6

**TECHNICAL** INFORMATION

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**TECHNICAL** INFORMATION

- Accuracy

**Technical Information** 

# Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the Canadian Diabetes Association (www.diabetes.ca), some of the most common symptoms are:

#### Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure
- irritability
- extreme hunger
- dizziness

#### Ketones (Ketoacidosis):

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

#### WARNING

If you are experiencing any of these symptoms, test your blood glucose. 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.

#### excessive thirst blurred vision

(Hyperglycemia):

High blood glucose

• frequent urination

- increased fatigue
- hunger

# **Specifications**

Test Sample: Venous or capillary whole blood Test Result: Referenced to plasma/serum glucose Sample Volume: 0.6 µL Measuring Range: 0.6 - 33.3 mmol/L Countdown Time: 5 seconds Memory: Stores most recent 800 test results Battery Type: Two 3-volt lithium batteries (DL2032 or CR2032) Battery Life: Approximately 1000 tests (1 yr. average use) Control Solution Operating Temperature Range: 15°C - 35°C Meter Operating Temperature Range: 5°C - 45°C Meter Operating Humidity Range: 10%–93% RH Dimensions: 80 mm (H) x 53 mm (W) x 12.7 mm (T) Weight: 1.6 oz. (45 grams) Meter Life: 5 years Sound Output: 55 to 80 dBA at a distance of 10 cm Electromagnetic Compatibility (EMC): The CONTOUR®NEXT

meter complies with the electromagnetic requirements specified in ISO 15197:2013. 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 meter. The CONTOUR NEXT meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The CONTOUR NEXT meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference do not use the CONTOUR NEXT meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

**TECHNICAL** INFORMATION

Symptoms of High or Low Blood Glucose

**Principles of the Procedure:** The CONTOUR®NEXT 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.

**Comparison Options:** CONTOUR®NEXT system evaluations should be done 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% to 7% per hour).<sup>5</sup>

#### Limitations

**Preservatives:** Blood may be collected by health care professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.

Peritoneal Dialysis Solutions: Icodextrin does not interfere with CONTOUR®NEXT test strips.

**Interference:** Reducing substances occurring in the blood naturally or from therapeutic treatments will not significantly affect results. See reagent test strip insert for more information.

Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

#### References

- Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
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- **3.** Desachy A, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. *Mayo Clinic Proceedings*. 2008;83(4):400-405.
- Cryer PE, Davis SN. Hypoglycemia. In: Kasper D, et al, editors. *Harrison's Principles of Internal Medicine*. 19th edition. New York, NY: McGraw Hill; 2015. http://accessmedicine.mhmedical.com/content.aspx? bookid=1130&sectionid=79753191
- **5.** Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.

**Principles of the Procedure** 

**TECHNICAL** INFORMATION

# Warranty

**Manufacturer's Warranty:** Ascensia 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, Ascensia 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. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR®NEXT test strips and CONTOUR®NEXT control solutions).
- **3.** Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
- 4. Ascensia Diabetes Care has not validated the performance of the CONTOUR®NEXT blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore does not warrant the performance of the CONTOUR NEXT 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.** Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR®NEXT meter or test results when used with any control solution other than CONTOUR®NEXT control solution.
- 6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any software other than GLUCOFACTS®DELUXE diabetes management software (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

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

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

**For warranty service:** Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this instrument. See the back cover for contact information.

Warranty

**TECHNICAL NFORMATION** 

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