

Contour[®] plus

Blood Glucose Monitoring System



The NO CODING
technology
provides accurate
and fast blood
glucose monitoring



Uses only CONTOUR[®]PLUS blood glucose test strips

USER GUIDE

INTENDED USE

The CONTOUR®PLUS blood glucose monitoring system (meter, test strips and control solution) is intended for self-testing by persons with diabetes and by health care professionals to monitor glucose concentrations in venous whole blood and in fresh capillary whole blood drawn from the fingertip or palm, arterial and venous whole blood or neonatal blood. It is for the quantitative measurement of glucose in whole blood from 0.6 mmol/L to 33.3 mmol/L.

It is intended for *in vitro* diagnostic use only.

The CONTOUR PLUS 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 PLUS blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus.

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 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

Talk to Your Health Care Professional


- 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 reading, 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 handling the meter, lancing device or test strips.
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning.
- The lancing device provided with your kit 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 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.
- Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility.
- 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

- The CONTOUR®PLUS meter only works with CONTOUR®PLUS test strips and CONTOUR®PLUS control solution.
-  Read your CONTOUR PLUS 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 for replacement parts. See the back cover for contact information.
- Always keep the CONTOUR PLUS 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 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 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®PLUS meter is connected to a computer.
- Use only approved equipment from the manufacturer or certified body such as UL or TUV.
- Your CONTOUR PLUS meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter of blood).
 - ✦ Results in mmol/L will **always** have a decimal point;
 - ✦ Results in mg/dL will **never** have a decimal point.

Example: 5.2 mmol/L or 93 mg/dL

 - ✦ Check your display screen to be sure the results are shown the right way. If not, contact Customer Service. See the back cover for contact information.
- The CONTOUR®PLUS blood glucose monitoring system has a measuring range of 0.6 mmol/L to 33.3 mmol/L. This means if your blood sugar result is less than 0.6 mmol/L or more than 33.3 mmol/L your meter is unable to display a number and will display a flashing “LO” or “HI” in the center of your meter display screen.

Your Meter Features

Easy: The CONTOUR®PLUS blood glucose monitoring system is about simplicity. You will notice this the first time you use it.

Automatic: The CONTOUR®PLUS 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 PLUS 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.

CAUTION: Your CONTOUR PLUS meter ONLY works with CONTOUR PLUS test strips and CONTOUR PLUS control solution.



WARNING: Potential Biohazard

Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases.^{5,6}

NOTE: CONTOUR PLUS blood glucose strip (FAD glucose dehydrogenase method) is abbreviated in this user guide as test strip.

Table of Contents

Intended Use, Important Safety Information	i
Precautions	iii
Your Meter Features.....	v
Your CONTOUR®PLUS Meter	2

Getting Ready to Test.....	6
Getting the Blood Drop	11
Testing Your Blood	11
Alternative Site Testing (AST) - Palm	15
Control Solution Testing	20

Setting the Time, Date and Sound.....	24
Set-up for Basic (L-1) and Advanced (L-2) Modes	27
Personalising LO, HI and Reminder Settings	28
Using Marker and Reminder Features	30
Viewing Results: Basic Mode.....	36
Viewing Results: Advanced Mode	39

Error Codes and Symbols.....	42
Changing the Batteries	46
Caring for Your Meter and Cleaning Your Meter.....	48
Symptoms of High or Low Blood Glucose	49
Specifications.....	50
Service Information	55
Warranty	56
Supplies.....	58

Your CONTOUR®PLUS Meter



Using the Meter Buttons

- Press and hold the **M** button **until the meter turns on.**
- Press and hold the **M** button **until the meter turns off.**
- The **▲** or **▼** scroll buttons on the meter allow you to scroll. You can hold the **▲** or **▼** button to scroll continuously through a list.
- Press the **M** button to select the option that appears.
- To access Setup, with the meter off, press and hold **M** for 3 seconds. See page 24.

Your CONTOUR®PLUS Test Strip



Your Meter Display


The picture below shows all the symbols that appear on your meter display. To view, with the meter off, press and hold ▲ or ▼. All display segments will appear for 10 seconds. If you need more than 10 seconds to check the display, press and hold ▲ or ▼ again.



While all characters are displayed, it is very important to verify that **0.00** is fully displayed. If there are missing segments, see **Error Codes and Symbols** (pages 42-45). This may affect the way you see your results.

Icon	What it Means
	Top area on the display presenting date and time.
	Pre-meal result marker.
	Post-meal result marker.
	Identifies a Diary entry.
	Indicates a reminder has been set.
	Center area on the display that shows either your test result or any error codes.
	The meter is ready to test.
	Control solution result marker.
	Indicates it is too cold or too hot for your meter to test accurately.
	Indicates Average.
	Results are displayed as mmol/L or mg/dL. The 7 appears when viewing 7 day HI-LO summary.
	Day/month format.
	The batteries are low and need to be changed, and will remain on display until batteries are changed.
	Appears if the meter is in 12 hour setup.
	Indicates sound is turned on.

Getting Ready to Test

 Read your CONTOUR PLUS 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 PLUS meter only works with CONTOUR PLUS test strips and CONTOUR PLUS control solutions.

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

WARNING

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning. See page 48.
- 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.


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.

WARNING: Potential Biohazard

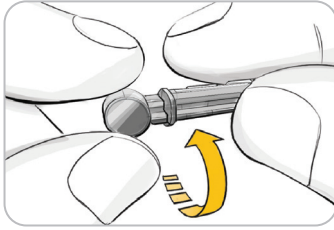
The lancing device provided with your kit is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.

WARNING

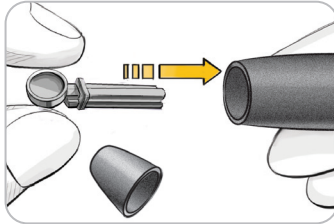
- Dispose of the used lancet as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Use a new lancet each time you test.

For Alternative Site Testing instructions, see page 15.

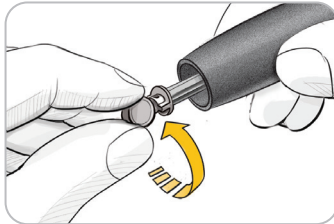
1. Remove the endcap from the lancing device.



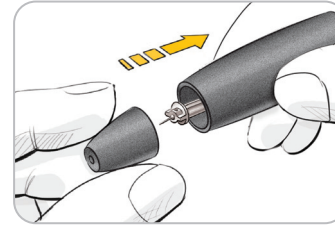
2. Loosen the round protective cap on a lancet by rotating it $\frac{1}{4}$ turn, but do not remove it.



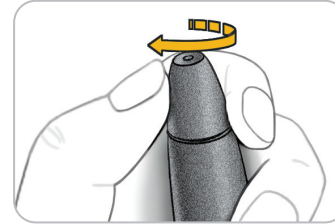
3. Insert the lancet firmly into the lancing device until it comes to a full stop.



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



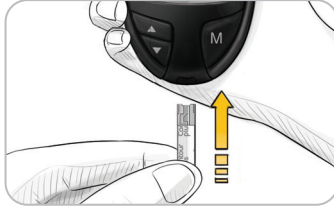
5. Replace the endcap.



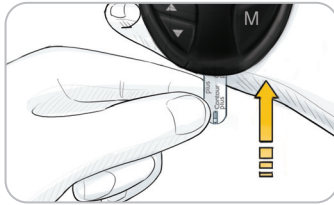
6. Rotate the endcap dial to adjust the puncture depth. The amount of pressure applied to the puncture site also affects puncture depth.

Inserting the Test Strip

1. Remove a CONTOUR®PLUS 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 toward the meter.



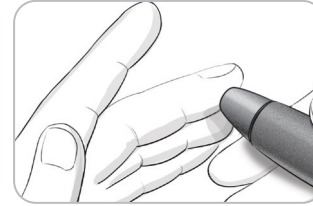
3. Insert the grey square end firmly into the test strip port until the meter beeps.



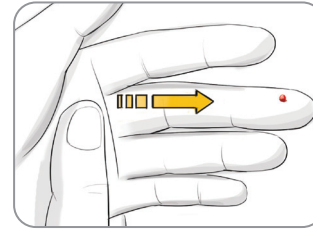
This will turn the meter on. An image of a test strip with a flashing blood drop  will appear letting you know the meter is ready to test.

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.

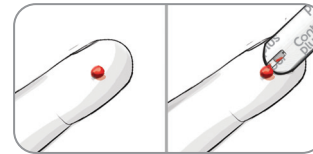
Getting the Blood Drop - Fingertip Testing



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

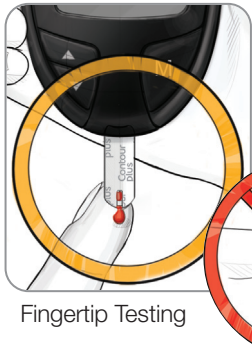


2. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site.



3. Test immediately after a good blood drop has formed.

Suggested drop size



Fingertip Testing

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

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

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



If the first blood drop is not enough, the meter may beep twice and display a strip underfill screen image

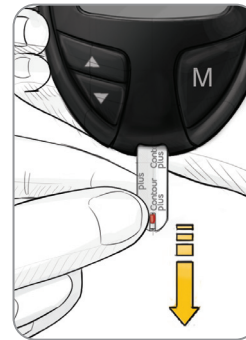


You have about 30 seconds to apply more blood to the same strip. If you are not able to apply enough blood within that time, an **E2** error code will be displayed. Dispose of the used test strip as medical waste or as advised by your health care professional and start over with a new strip.



5. After a beep, you will see the meter count down 5 seconds and your blood test result is displayed and automatically stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.

NOTE: You can set your meter to use meal marker options. See Advanced Mode settings (L-2) on pages 27 - 29. If you want to mark your result you will need to do it before removing the test strip.



6. Remove the test strip to turn your meter off. Dispose of the used test strip as medical waste or as advised by your health care professional.
7. 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.

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, approximately 3.9 - 6.1 mmol/L in the fasting state.⁴

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.

Alternative Site Testing (AST) - Palm

WARNING

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

IMPORTANT: For Alternative Site Testing, use the clear endcap. Your CONTOUR®PLUS meter can be used for fingertip or palm testing. See the insert for detailed instructions on 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 (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 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 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 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. **Refer to the lancing device insert for detailed instructions.**

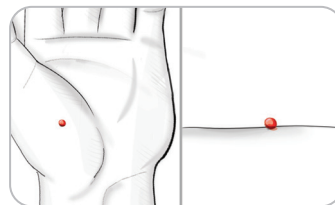


3. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones and tendons.

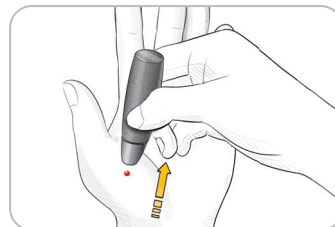


4. Press the lancing device firmly against puncture site and then press the release button.

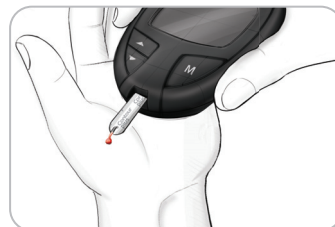
The lancing device graphics are for illustration purposes only.



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



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



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

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

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

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

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



If the first blood drop is not enough, the meter may beep twice and display a strip underfill screen image



You have about 30 seconds to apply more blood to the same strip. If you are not able to apply enough blood within that time, an E 2 error code will be displayed. Dispose of the used test strip as medical waste or as advised by your health care professional and start over with a new strip.

Please see Expected Test Result Values on page 14.

Ejecting and Disposing of the Used Lancet



1. 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, if 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.



WARNING: Potential Biohazard

- The lancing device, lancets and test strips are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.^{5,6}
- Always dispose of the used test strip and lancet as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Use a new lancet each time you test.

Control Solution Testing

⚠️ WARNING

Shake the control solution well before testing.



CAUTION: Use only CONTOUR®PLUS control solution with your CONTOUR®PLUS test strips. Using any other control solution may 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 right.
- 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.

20

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

1. Remove a 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 into the test strip port on the meter until the meter beeps.



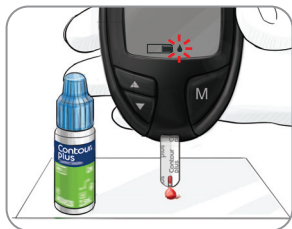
4. This will turn the meter on. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.



5. 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.

21



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 will count down for 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 Diary. Control test results will not be included in your blood glucose averages or the 7 day HI-LO summary.

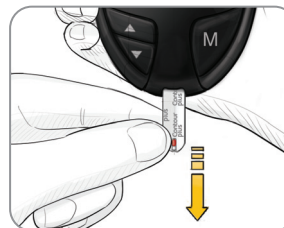
NOTE: The ✓ does not indicate the control test result is within the specified range. It only marks it as a control solution test. It will not be included in your averages.

11. Compare your control test result with the range printed on the test strip bottle or the bottom of the test strip box.



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®PLUS meter for blood glucose testing until you resolve the issue. Contact Customer Service. See the back cover for contact information.



12. Remove the test strip and dispose of it as medical waste or as advised by your health care professional.

IMPORTANT: To ensure accuracy of your blood glucose test results and accuracy of your control test results, use only CONTOUR®PLUS control solutions.

Setting the Time, Date and Sound

Your CONTOUR®PLUS meter allows you to set the date, time, and sound as you like them.

- You can view 12 or 24 hour time;
- month/day or day.month; and
- choose to have your meter beep or not.

To get into set-up mode when the meter is off, press and hold **M** for 3 seconds. A complete display will briefly appear, then numbers will flash in the top left corner of the display.

Setting the Time



With the **24H** flashing on the display, press ▲ or ▼ to select the 12H (with AM and PM) or 24H setting.



Press **M** to set.



The number in the **hour** position will now flash. Press ▲ or ▼ until you reach the current hour.

Press **M** to set.



The **minute** will now flash. Press ▲ or ▼ to select the current minute.

Press **M** to set.



If you selected a 12 hour time setting, the **AM** or **PM** will now flash. Press ▲ or ▼ to select AM or PM.

Press **M** to set.

Setting the Month and Day Format



d.m will now flash on the display. Press ▲ or ▼ to select the format you wish (m/d for month/day format or d.m for day.month format).

Press **M** to set.



Setting the Date



The **year** will be flashing. Press ▲ or ▼ to select the current year.

Press **M** to set.



The **month** will now flash. Press ▲ or ▼ to select the month.

Press **M** to set.



The **day** will now flash. Press ▲ or ▼ to select the day.

Press **M** to set.

Setting the Sound



The flashing bell symbol will now appear on the display along with the word **On**. This option controls whether you want to hear the beep sound during testing.



To turn the beep sound off during testing, press **▲** or **▼** to display **OFF**. Press **M** to set.



After setting the sound, **L-1** will flash. To keep your meter in Basic Mode, press **M** to set. To change your meter to Advanced Mode, press **▲** or **▼** to change to **L-2**, and press **M** to set.



If you are using Basic Mode (**L-1** will appear on your display), you have completed your meter set-up.

Set-up for Basic (L-1) and Advanced (L-2) Modes

Your new CONTOUR®PLUS meter is pre-set for the Basic Mode and offers the same easy test procedure in either the Basic or Advanced Mode.

BASIC MODE (L-1)

- 7 day HI and LO summary
- 14 day average
- 480 test result memory

ADVANCED MODE (L-2)

- 7 day HI and LO summary
- 7, 14, and 30 day averages
- 480 test result memory
- Pre- and post-meal markers
- 30 day pre- and post-meal averages
- Selectable post-meal reminders 2.5; 2.0; 1.5; 1.0 hours.
- Personal HI and LO test settings



Your meter is pre-set to Basic Mode. If you have set your meter to the Advanced Mode, and want to return to Basic Mode:

1. Press **M** to turn your meter on. Wait to see the flashing test strip.
2. Press and hold **▲** or **▼** for 3 seconds.
3. **L-2** will flash.
4. Press **▲** or **▼** to change to **L-1**.
5. Press **M** to set.



To set your meter to Advanced Mode, and take advantage of meal markers and other functions available to you:

1. Press **M** to turn your meter on. Wait to see the flashing test strip.
2. Press and hold **▲** or **▼** for 3 seconds.
3. **L-1** will flash.
4. Press **▲** or **▼** to change to **L-2**.
5. Press **M** to set.

Personalising LO, HI and Reminder Settings



If you selected Advanced Mode (L-2 on your display) you can change your meter's personal low and high blood glucose settings. By personalising these settings, your CONTOUR®PLUS meter will help you track these HI and LO results.



The LO setting will flash (default 4.0 mmol/L). To change this setting, press ▲ or ▼ until you reach your desired LO setting, and then press **M** to set. (The range of values for LO is 3.3 - 5.0 mmol/L).



Your HI blood glucose setting will now flash (default 10.0 mmol/L). To change, press ▲ or ▼ until you reach your desired HI setting. Press **M** to set. (The range of values for HI is 5.6 - 13.9 mmol/L).

Post-Meal Test Reminder Set-up



To change the reminder time for post-meal testing, press ▲ or ▼ to display the options available. Select 2.5; 2.0; 1.5 or 1.0 hour(s) to set your post-meal reminder (default is 2.0 hours). Press **M** to set.





You have now completed your CONTOUR®PLUS meter set-up for Advanced Mode!


Using the Markers



If you have set up your meter in Advanced Mode, your meter will display three markers after you test your blood.

 **Pre-meal** = Marks a test result that was taken before a meal.

 **Post-meal** = Marks a test result that was taken after a meal.

 **Diary** = The diary marker can be used to mark any result as being unique or different in some way, and for which you may want to make notes in your diary. Seeing a result with this symbol next to it in the memory will help remind you that there is more information recorded about this test result.

Please see the following to use these options.


If you do not want to mark the test result

Remove the used test strip to automatically save the test result in the meter memory with no markers. This will also turn the meter off.


If you want to mark the test result

Before you remove your test strip, press **▲** or **▼** to select the marker you want to set. The marker will flash.




To mark a result with the pre-meal marker, press **M** when the  flashes.




The  will then flash. This feature allows you to set a reminder to remind you to run a post-meal test.


The reminder is available only after setting a pre-meal marker.



If you want to set the reminder, press **M**. The  will appear and stop flashing.

If you do not want to set the reminder, press **▲** or **▼** and the  will disappear. Press **M** to set.

To mark a result with the post-meal marker, press **▲** or **▼** until the  flashes. Press **M** to set.

To mark a result with the diary, press **▲** or **▼** until the  flashes. Press **M** to set.

Using the Reminder Feature



When the reminder sounds, the meter will automatically turn on. The reminder will beep 20 times, and the display will show the pre-meal test result you marked when you set the reminder. Pressing any button will silence the reminder.

You can now run another test by placing a test strip in the test strip port and following the testing instructions (page 6).



When you have completed this test and the result is shown on the display, I will flash. To mark this test as a post-meal result, press **M**. If you do not want to mark this test, remove the test strip to turn the meter off. Dispose of the used test strip as medical waste or as advised by your health care professional.

If you decide not to test after the reminder sounds, press any button to turn your meter off.

The meter will only set one reminder at a time. It will remember the last reminder set.

NOTE: If sound is turned off, the Reminder sound will not beep.

To Cancel a Reminder











When the meter is off, press **M** to turn on the meter. The date and time will appear along with the I .

Press \blacktriangle or \blacktriangledown twice and the reminder icon will disappear.

Press **M** to cancel the reminder.

After performing a test

To Mark Results >	You Will See >	To Set >	You Will See >	What It Means
Pre-Meal Press ▲ or ▼	 (Flashing)	Press M		Result is marked as a pre-meal test. You can now set a reminder.
Reminder Press ▲ or ▼	 (Flashing)	Press M		Reminder is set to go off in the amount of time you have set (1.0 - 2.5 hours) to remind you to run a post-meal test.
Post-Meal Press ▲ or ▼	 (Flashing)	Press M		Result is marked as a post-meal test.*
Diary Press ▲ or ▼	 (Flashing)	Press M		Result is marked in memory as unique. You should note this in your diary.

*Post-meal glucose measurements should be made 1-2 hours after the beginning of the meal.⁷

Viewing Basic Mode Results

Press **M** to turn your meter on. Press **M** again to view the memory.



The **14 day average** will appear in the center of the display with the number of results shown at the top of the display. Control results are not included in this 14 day average.



Press **▲** to view the **7 day high and low summary**.

At the top of the display you will see the number of HI results (above 10.0 mmol/L) and LO results (below 4.0 mmol/L) during the preceding 7 day period and the total number of results during that period.



Press **▼** twice to review **previous results**.

Results will be shown starting with the most recent. Each result will show the date and time the test was taken.

You can press **▲** or **▼** to scroll forward or backward through the results.



When **End** appears on the display, you have viewed all of the results in the memory.

NOTES:

- Averages include the specified time period plus the current day.
- The meter will hold 480 results in the memory. When the maximum is reached, the oldest test result will be removed as a new test is completed and saved to the memory.
- Press **M** to turn the meter off, or it will automatically turn off after 3 minutes.
- \bar{n} represents the number of test results.

Viewing Advanced Mode Results

In Advanced Mode (L-2), you have all of the options described in Basic Mode plus additional items available.



Press **M** to turn your meter on. Briefly press **M** again to view the **14 day average** including the number of results used to obtain the average.



Press **▼** to review previous results.

Results will be shown starting with the most recent. Each result will show the date and time the test was taken.

You can press **▲** or **▼** to scroll forward or backward through the results.

When **End** appears on the display, you have viewed all of the results in the memory.

Viewing Advanced Mode Averages

Press **M** to turn your meter on. Press **M** again to view the **14 day average** including the number of results used to obtain the average.



Press ▲ to view the 7 day high and low summary.

At the top of the display you will see the number of HI and LO results. In the center of the display is the total number of results.



Press ▲ to view the 7 day average.

You will see the average in the center of the display and the number of results along the top.

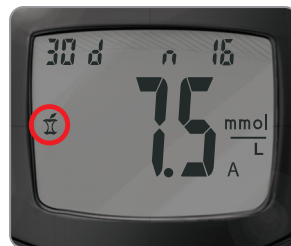


Press ▲ to view the 30 day average.

This will display the average in the center and the number of readings along the top.



Press ▲ again to view the 30 day average of results marked with a **pre-meal marker**.



Press ▲ again to view the 30 day average of results marked with a **post-meal marker**.









Press ▲ again and you will see **End**.




Press **M** to turn the meter off, or it will automatically turn off after 3 minutes.

Error Codes and Symbols



If you do not resolve the problem, contact Customer Service. See the back cover for contact information.

What You See	What It Means	What You Should Do
 (will remain on the display)	Low batteries.	Replace the batteries as soon as possible.
 (will flash for 10 seconds and then the meter will turn off)	Dead batteries.	Replace the batteries.
	The meter is ready to test.	Proceed with the testing of your blood.
	Not enough blood sample.	Add more blood within 30 seconds.
E1 	Temperature out of range.	Move to an area that is within the operating range for the meter: 5°C – 45°C. Let the meter adjust to this temperature for 20 minutes before performing a test.
E2 	The test strip has not filled enough for an accurate test. Insufficient blood drop.	Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing.

If you do not resolve the problem, contact Customer Service. See the back cover for contact information.

What You See	What It Means	What You Should Do
E3 	<ul style="list-style-type: none"> The meter is sensing a used test strip. The wrong control solution was used. 	<ul style="list-style-type: none"> Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing. If control testing, make sure to use CONTOUR®PLUS control solution.
E4 	Test strip not inserted correctly.	Remove and reinsert the test strip properly (see page 10).
E5 E9 E6 E12 E8 E13	Potential software or hardware issue.	Remove the test strip and retest using a new test strip. If you continue to have problems, contact Customer Service. See the back cover for contact information.
E7 	Incorrect test strip.	Remove the test strip and retest using a new test strip. Make certain that you are using a CONTOUR®PLUS test strip.
E10	Invalid date or time.	This error occurs only in Communication mode. See pages 24 - 25 to reset the date or time. If you continue to see this error, please contact Customer Service. See the back cover for contact information.

If you do not resolve the problem, contact Customer Service. See the back cover for contact information.



What You See	What It Means	What You Should Do
E11	Abnormal result.	Remove the test strip and retest using a new test strip. Be sure you wash and dry your hands well and carefully follow instructions in this user guide. Only the CONTOUR®PLUS test strips should be used.
 (When you only see "HI")	Test result is above 33.3 mmol/L.	<ul style="list-style-type: none"> Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.
 (When you only see "LO")	Test result is below 0.6 mmol/L.	<ul style="list-style-type: none"> Follow medical advice immediately.
Some display segments do not appear when the meter initially turns on.	Possible meter electronics failure.	Compare meter display with the illustration on page 4. If the display is not correct, contact Customer Service. See the back cover for contact information.
Results are not displayed in expected units of measure (mmol/L).	This may affect the way you see your results.	Contact Customer Service. See the back cover for contact information.

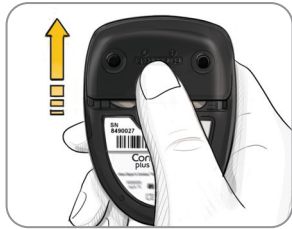
If you do not resolve the problem, contact Customer Service. See the back cover for contact information.

What You See	What It Means	What You Should Do
Control test result is out of range (too high or too low).	Test strip or control solution is past the expiration date or is past the discard date.	Check all expiration dates and discard dates. Do not use expired testing materials.
	Test strip is deteriorated due to heat or exposure to moisture.	Run another control test with a new test strip and control solution.
	Control solution is not at room temperature or may not be mixed well.	Shake the control solution bottle well, about 15 times before every use.
	Incorrect control solution was used.	Make sure you are using CONTOUR®PLUS control solution.
	Meter could be damaged.	If result is still out of range, contact Customer Service. See the back cover for contact information.

Changing the Batteries

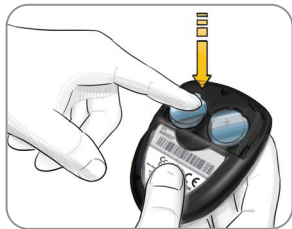


Batteries should be replaced when the meter continually displays  or the meter briefly shows  and then turns off (**See Error Codes and Symbols, page 42**).

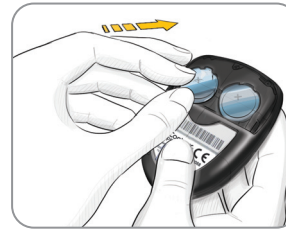


1. Turn off your meter before changing your batteries.
2. Press firmly on the battery cover and slide in the direction of the arrow.

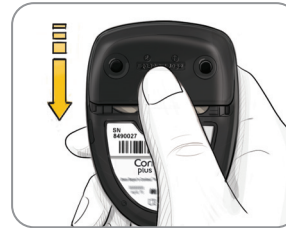
NOTE: If you put the new batteries in the meter within 5 minutes of taking the old ones out, all your settings and results will be saved. If you take more than 5 minutes, you will need to reset the date and time although your other settings and results will be saved.



3. Remove the old batteries by pressing the top of the battery which will raise the bottom of the battery up.



4. Place new batteries under the prongs and into the battery compartment with the “+” side up. [Use two 3-volt (DL2032 or CR2032) lithium batteries.]



5. Slide the battery cover back into place, lining up with the open slots, and close firmly.

WARNING

Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your doctor or poison control center. Discard batteries according to your local environmental regulations.

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.

Cleaning Your Meter

The exterior of the CONTOUR®PLUS meter can be cleaned using a moist (not wet) lint-free tissue with a mild detergent or disinfectant solution, such as 1 part bleach mixed with 9 parts water. Wipe dry with lint-free tissue after cleaning.

CAUTION:

Do not allow cleaning solution to run in or around the buttons, battery cover or test strip port. Doing so may cause a malfunction.



WARNING

Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases. The user should follow the recommendations for prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens.

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. Some of the most common symptoms are:

Low blood glucose (Hypoglycaemia):

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

High blood glucose (Hyperglycaemia):

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

Ketones (Ketoacidosis):

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



WARNING

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

System Specifications

Test Sample: Venous, arterial or capillary whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 0.6 - 33.3 mmol/L

Results: 5-second countdown

Memory Feature: Stores most recent 480 test results

Battery Type: Two 3-volt lithium batteries, 225 mAh capacity (DL2032 or CR2032)

Battery Life: Approximately 1000 tests (1 yr. average use)

Meter Operating

Temperature Range: 5°C - 45°C

Control Solution

Operating Temperature Range: 15°C - 35°C

Humidity: 10% - 93% RH

Dimensions: 77 mm (H) x 57 mm (W) x 19 mm (T)

Weight: 47.5 grams (1.7 oz.)

Sound Output: 40-80 dBA

Electromagnetic Compatibility (EMC):

The CONTOUR®PLUS meter complies with the electromagnetic requirement 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 PLUS meter. The CONTOUR PLUS 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 PLUS meter

meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR®PLUS meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
















Principles of the Procedure: The CONTOUR PLUS blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.


Comparison Options: The CONTOUR PLUS system is designed for use with capillary and venous 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).⁸

Symbols Used

The following symbols are used throughout the product labeling for the CONTOUR®PLUS blood glucose monitoring system (meter, lancet and lancing device packaging and labeling; and reagent and control solution packaging and labeling).

Symbol	What it Means	Symbol	What it Means
	Use by date (last day of month)		Control Range Normal
	Batch code		Control Range Low
	Do not reuse		Control Range High
	Consult instructions for use		Temperature limitations
	In Vitro Diagnostic Medical Device		
	Manufacturer		Sterilized using irradiation
	Catalogue number		Warning
	Control Discard Date		Shake 15 times

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

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

Contour
plus

Technical Information

Accuracy

The CONTOUR®PLUS blood glucose monitoring system was tested in 100 capillary blood samples using 600 CONTOUR®PLUS test strips. Two replicates were tested with each of 3 lots of CONTOUR PLUS 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®PLUS meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	174 of 198 (87.9%)	198 of 198 (100%)	198 of 198 (100%)

Table 2 – System accuracy results for glucose concentration ≥ 5.55 mmol/L

Difference range in values between YSI® laboratory reference method and CONTOUR PLUS meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	361 of 402 (89.8%)	400 of 402 (99.5%)	402 of 402 (100%)

Table 3 – System accuracy results for glucose concentrations between 1.2 mmol/L and 30.2 mmol/L

Within ± 0.83 mmol/L or ± 15%	600 of 600 (100%)
-------------------------------	-------------------

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 ± 0.83 mmol/L for glucose values less than 5.55 mmol/L, and within ± 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 216 lay persons showed the following results: 100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.8% 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®PLUS blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.3 to 17.9 mmol/L. Multiple replicates (n=300) were tested using multiple CONTOUR®PLUS blood glucose meters and 3 lots of CONTOUR®PLUS blood glucose test strips. The following precision results were obtained.

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

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
2.5	0.07	0.06 - 0.08	2.8
4.7	0.12	0.10 - 0.14	2.5
7.3	0.11	0.09 - 0.13	1.5
11.7	0.16	0.14 - 0.18	1.3
18.5	0.27	0.23 - 0.31	1.5

Intermediate precision (which includes variability across multiple days) was evaluated using 3 control solutions. With each of 3 lots of CONTOUR PLUS 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 PLUS meter using CONTOUR PLUS test strips

Control Level	Mean, mmol/L	Standard Deviation, mmol/L	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
Low	2.4	0.04	0.03 - 0.04	1.5
Normal	7.2	0.08	0.07 - 0.10	1.2
High	21.5	0.32	0.28 - 0.38	1.5

Service Information

If you have a problem and none of the problem solving steps in this user guide help, contact Customer Service. See the back cover for contact information. We have trained specialists to help you.

Important

- **Speak to a 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®PLUS blood glucose meter and CONTOUR PLUS test strips available when you phone. It would also be helpful to have a bottle of CONTOUR PLUS control solution nearby.**

Check List

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



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

2. Locate the CONTOUR PLUS test strips' expiry date on the bottle. _____
3. Check the battery icon on the display. (See page 46, Changing the Batteries.)

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®PLUS test strips and CONTOUR®PLUS 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 no knowledge of the performance of the CONTOUR®PLUS blood glucose meter when used with any test strips other than

CONTOUR®PLUS test strips, and therefore does not warrant the performance of the CONTOUR®PLUS meter when used with any test strips other than CONTOUR PLUS test strips or when the CONTOUR PLUS test strip is altered or modified in any manner.

5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR PLUS meter or test results when used with any control solution other than CONTOUR®PLUS control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR PLUS meter or test results when used with any software other than the CONTOUR DIABETES app (where supported) or the GLUCOFACETS™DELUXE diabetes management software (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS 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 back cover for contact information.

Supplies

Replacement Parts

Item

Two 3-volt lithium batteries DL2032 or CR2032

CONTOUR PLUS user guide

CONTOUR PLUS test strips

CONTOUR PLUS normal control solution

CONTOUR PLUS high control solution

CONTOUR PLUS low control solution

CONTOUR PLUS quick reference guide

Lancing device

Lancets

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Index

After Meal Marker (Post-meal).....	27
Alternative Site Testing (AST)	15
Averages.....	40
Batteries	46
Low Batteries	46
Replacement	46
Before Meal Marker (Pre-meal).....	27
Care and Maintenance	48
Cleaning Your Meter.....	48
Control Solution Testing	20
Diary	30
Diary marker.....	30
View Test Results in Memory	36
Errors.....	42
Lancing.....	7
LO and HI Settings.....	28
Meter Settings.....	24
Reminders (Test Reminders).....	32
Getting a Reminder	32
Service Information	55

Setup.....	24
Date.....	25
Sound.....	26
Time	24
Specifications.....	50
Symptoms of High or Low Blood Glucose.....	49
Technical Information	53
Test Reminders.....	29
Getting a Reminder	32
Testing Your Blood Sugar	11
Getting Ready to Test.....	6
Test Results.....	14
Warranty	56

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