

Contour[®] plus ELITE[™])

Blood Glucose Monitoring System

Works with the CONTOUR[®]DIABETES app available for download from the App StoreSM or on Google PlayTM.



Second-Chance[™]
sampling

Uses only CONTOUR[®]PLUS
blood glucose test strips.

USER GUIDE

INTENDED USE

The CONTOUR®PLUS ELITE blood glucose monitoring system is intended to be used for the measurement of blood glucose in both insulin and non-insulin treated patients with diabetes as an aid for patients and their health care professionals in monitoring the effectiveness of the patient's diabetes control. The CONTOUR PLUS ELITE blood glucose monitoring system is intended for self-testing by persons with diabetes and health care professionals in venous blood and in fresh capillary whole blood drawn from the fingertip or palm. The CONTOUR PLUS ELITE blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use).

The CONTOUR PLUS ELITE blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). The CONTOUR®PLUS test strips are for use with the CONTOUR®PLUS ELITE blood glucose meter to quantitatively measure glucose in venous blood and fresh capillary whole blood drawn from the fingertips or palm.

The meter is for the quantitative measurement of glucose in whole blood from 10 mg/dL–600 mg/dL.

The system is intended for in vitro diagnostic use only.

IMPORTANT SAFETY INFORMATION



WARNING

If your blood glucose reading is under the critical level you have established with your health care professional, follow their advice immediately.

If your blood glucose reading is over the recommended limit set by your health care professional:

1. Wash and dry your hands well.
2. Retest with a new strip.

If you get a similar result, follow your health care professional's advice immediately.

Serious Illness

The system should not be used to test critically ill patients. Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension and 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 setting any **Target Ranges** in your meter or in compatible Ascensia Diabetes Care software.
- Before changing your treatment or medication based on test results.
- About whether Alternative Site Testing (AST) is appropriate for you.
- Before making any other decision of medical relevance.

Potential Biohazard

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

- All blood glucose measuring systems are considered biohazardous. 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.
- The lancing device provided 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.
- Always dispose of used 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 that could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

LIMITATIONS

- **Altitude:** This system has not been tested at altitudes higher than 6301 metres.
- **Hematocrit:** CONTOUR PLUS test strip results are not significantly affected by hematocrit levels in the range of 0% to 70%.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

PRECAUTIONS

-  Read your CONTOUR PLUS ELITE user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing. Follow all instructions for use and care exactly as described to help avoid inaccurate results.
- Examine the product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips.
For replacement parts, contact Customer Service. See the back cover for contact information.
- Your CONTOUR PLUS ELITE meter works ONLY with CONTOUR PLUS test strips and CONTOUR®PLUS control solution.
- 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. Do not place or store other items or medications in the test strip bottle. 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.
- Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.
NOTE: If this is the first time you are opening the control solution, write the date on the bottle.
- Do not use control solution that is more than 6 months past the date you first opened the bottle.
- 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 is designed to give accurate blood testing results at temperatures between 5°C and 45°C. If the meter or test strip is outside this range, you should not test until the meter and test strip are within this range. 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 attempt to perform a blood glucose test when the CONTOUR PLUS ELITE meter is connected to a computer.
- Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.
- Avoid use of electronic devices in very dry environments, especially if synthetic materials are present.
- Your CONTOUR PLUS ELITE meter has been preset and locked to display results in mg/dL (milligrams of glucose per decilitre of blood).
 - ❖ Results in mg/dL will **never** have a decimal point.
 - ❖ Results in mmol/L will **always** have a decimal point.

Example:  or 
- ❖ Check your display screen to be sure the results are shown correctly (mg/dL). If not, contact Customer Service. See the back cover for contact information.
- The CONTOUR PLUS ELITE blood glucose monitoring system has a measuring range of 10 mg/dL to 600 mg/dL.

- ❖ For results under 10 mg/dL or over 600 mg/dL:
 - If your blood glucose reading is under 10 mg/dL, the meter displays the **LO** screen. **Contact your health care professional immediately.**
 - If your blood glucose reading is over 600 mg/dL, the meter displays the **HI** screen. Wash your hands or the test site. Repeat the test with a new strip. If results are still over 600 mg/dL, **follow medical advice immediately.**

Your Meter Features

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

Automatic: The CONTOUR PLUS ELITE 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.



Second-Chance™ sampling allows you to apply more blood to the same test strip if the first blood sample is not enough. 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 PLUS ELITE blood glucose monitoring system. We are proud to be your partner in helping you manage your diabetes.

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

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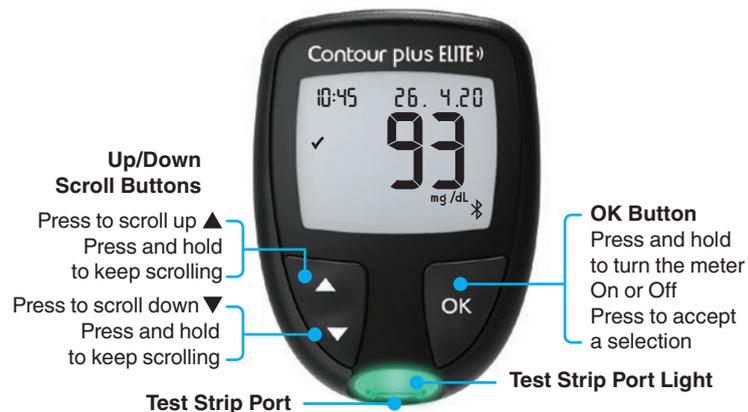
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Your CONTOUR PLUS ELITE meter



Navigate with 3 Buttons

Press and hold the **OK** button until the meter turns On.

Press and hold the **OK** button until the meter turns Off.

The ▲ and ▼ buttons on the meter allow you to scroll through the options. You can hold the ▲ or ▼ button to scroll continuously through a list.

Press the **OK** button to accept a selection.

To exit from the **Logbook** or **Averages** and return to the **Home** screen, press the **OK** button.

NOTE: When a symbol is blinking, you can select it.

Your CONTOUR PLUS ELITE meter Screen



Symbol	What the Symbol Means
↑	Blood glucose test result is above Target Range.
✓	Blood glucose test result is in Target Range.
↓	Blood glucose test result is below Target Range.
HI	Blood glucose test result is above 600 mg/dL.
LO	Blood glucose test result is below 10 mg/dL.
📖	Your Logbook .
⚙️	Meter Settings .

Symbol	What the Symbol Means
🍷	Fasting marker.
🍏	Before Meal marker.
🍷	After Meal marker.
✗	No marker selected.
🎯	A Target Range or Target Range setting.
💡	smartLIGHT ® target range indicator setting.
🧪	Meter is ready to test.
🧪	Add more blood to same test strip.
🧪	Control solution test result.
📶	Bluetooth ® symbol: indicates the Bluetooth wireless setting is On; the meter can communicate with a mobile device.
🔋	Indicates low batteries.
🔋	Indicates dead batteries.
⚠️	Indicates a meter error.
🕒	Reminder feature.
🔊	Sound feature.
7d Avg	7-, 14-, 30-, and 90-day averages.
∩	Total number of blood glucose readings used to calculate averages.

Your CONTOUR PLUS test strip



Grey Square End:
Insert this end into the test strip port

Sample Tip: Blood sample pulled in here

Check the Meter Display

Press and hold the **OK** button until the meter turns on, about 3 seconds.

The screen displays the **Power On Self Test**.



All symbols on the screen and the white strip port briefly light up. It is very important to verify that **8.8.8** displays fully and that the white light from the test strip port is visible.

If there are missing characters or if the strip port light is a colour other than white, contact Customer Service. This may affect the way you see your results.

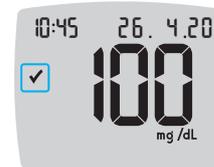
NOTE: Your meter comes with a pre-set time, date, and target range. You can change these features in **Settings**. See *Settings* on page 38.

Target Ranges

The meter compares your blood glucose results with a **Target Range** (for example, 70 mg/dL–130 mg/dL) to let you know if your test result is above, in, or below your Target Range.



↑ Above Your Target Range.



✓ In Your Target Range.



↓ Below Your Target Range.

You can change **Target Ranges** in **Settings** ⚙️. See *Settings* on page 38.

Meal Markers

During a blood glucose test, you can attach a **Meal Marker** to your blood glucose result when the **Meal Marker** feature in the meter is turned On. This feature lets you track your blood glucose levels over time with separate **Target Ranges** for **Fasting/Before Meal** and **After Meal** markers.

Your CONTOUR PLUS ELITE meter comes with **Meal Markers** turned Off. You can turn **Meal Markers** On and change **Target Ranges** in **Settings** ⚙️. See *Settings* on page 38.

Meal Marker choices if Meal Marker feature is On

Symbol	What the Symbol Means	Comparison/Target Range
	Fasting: Use the Fasting marker when testing blood glucose levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	If you mark your test result as Fasting , the meter compares your result against the Before Meal Target Range . Pre-set Before Meal Target Range: 70 mg/dL–130 mg/dL
	Before Meal: Use the Before Meal marker when testing blood glucose levels within 1 hour before a meal.	If you mark your test result as Before Meal , the meter compares your result against the Before Meal Target Range . Pre-set Before Meal Target Range: 70 mg/dL–130 mg/dL

Symbol	What the Symbol Means	Comparison/Target Range
	After Meal: Use the After Meal marker when testing blood glucose levels within 2 hours after the first bite of a meal.	If you mark your result as After Meal , the meter compares the result against the After Meal Target Range . Pre-set After Meal Target Range: 70 mg/dL–180 mg/dL
	No Mark Selected: Use the No Mark symbol when testing at times other than after fasting or before or after a meal.	If you do not mark the result, the meter compares your test result against the Overall Target Range . Pre-set Overall Target Range: 70 mg/dL–180 mg/dL

Get Ready to Test

 Read your CONTOUR PLUS ELITE user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing. Follow all instructions for use and care exactly as described to help avoid inaccurate results.

Examine the product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. For replacement parts, contact Customer Service. See the back cover for contact information.

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

Fingertip Testing

Ensure that you have the materials you need before you begin testing:

- CONTOUR PLUS ELITE meter.
- CONTOUR PLUS test strips.
- Lancing device and lancets from your kit, if provided.

To perform a quality control check, you also need CONTOUR PLUS control solution. Some supplies are sold separately. Contact Customer Service for questions about your kit. See the back cover for contact information.



WARNING: Potential Biohazard

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection, see page 54.
- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- For complete instructions on cleaning your meter, see page 54.

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 American Diabetes Association (www.diabetes.org), some of the most common symptoms are:

Low blood glucose (Hypoglycaemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure
- irritability
- 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 the critical level you have established with your health care professional or over the recommended limit, follow your health care professional's advice immediately.

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

Prepare 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 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.
-  Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.

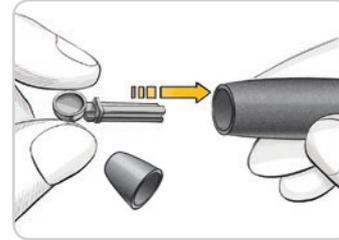
WARNING: Potential Biohazard

Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.

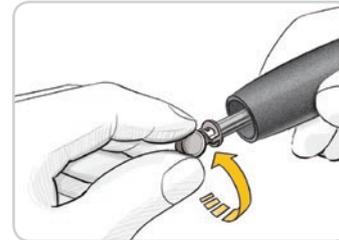
1. Remove the endcap from the lancing device.



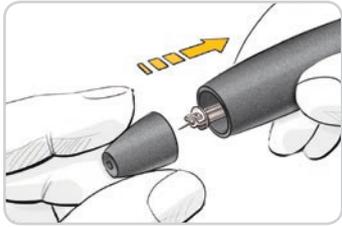
2. Loosen the round protective cap on a lancet by rotating the cap $\frac{1}{4}$ turn, but do not remove the cap.



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



4. Twist off the round protective lancet cap. Save the cap 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.

Insert the Test Strip

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiry dates on your test materials.



1. Remove a CONTOUR PLUS test strip from the bottle.
2. **Tightly close the bottle lid immediately after you have removed the test strip.**



3. Hold the test strip with the grey square end facing toward the meter.
4. Insert the grey square end firmly into the test strip port until the meter beeps.



The screen displays the blinking blood drop indicating it is ready to test a blood drop.

NOTE: After you insert the test strip, apply blood to the test strip within 3 minutes or the meter turns off. Remove the test strip and reinsert it to begin a test.

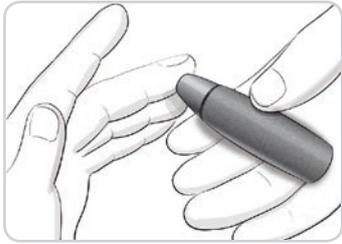
Get the Blood Drop: Fingertip Testing

NOTE: For Alternative Site Testing instructions, see page 24.

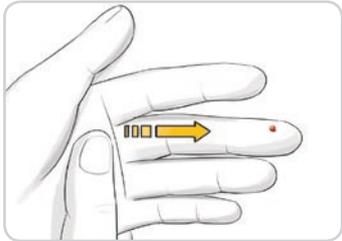


WARNING: Potential Biohazard

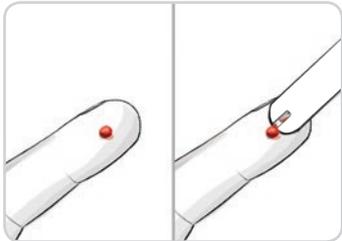
Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.



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 drawn into the test strip through the tip.

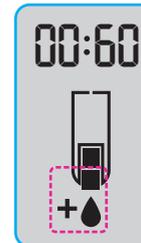


CAUTION: Do not press the tip of the test strip against the skin or place the blood on top of the test strip. These actions could lead to inaccurate results or errors.



5. Hold the tip of the test strip in the blood drop until the meter beeps.
NOTE: If the **Meal Marker** feature is On, do not remove the test strip until you select a **Meal Marker**.

Second-Chance sampling—Apply More Blood



1. If the meter beeps twice and the screen displays a blinking blood drop with a plus sign, the test strip does not have enough blood.
 2. Apply more blood to the **same** test strip within 60 seconds.
- NOTE:** If the screen displays an **E 1** error message, remove the strip and start with a new strip.

The meter displays your blood glucose result. If **Meal Markers** are On, the **Meal Marker** symbol is blinking.

Select a Meal Marker

NOTE: During a blood glucose test, if **Meal Markers** are On, you can select a **Meal Marker** when the meter displays your result. **You cannot select a Meal Marker in the Settings screen.**

If the **Meal Marker** feature is On, a **Fasting** 🍷, **Before Meal** 🍏, **After Meal** 🍷, or **No Mark** ✕ marker is blinking on the blood glucose result screen. The meter suggests this **Meal Marker** based on the time of day and the meal period: breakfast, lunch, dinner, or overnight. For more information about Meal Markers, see page 8.

Example:



Do not press the OK button or remove the test strip yet.

You can select the blinking marker or choose a different **Meal Marker**.

To turn **Meal Markers** On, see *Set Meal Markers* on page 44.



1. If the blinking **Meal Marker** is the one you want, press the **OK** button

or

2. To select a different **Meal Marker**, press the ▲ or ▼ button on the meter to scroll between markers.



Example: If you scroll up to **Before Meal**, the **Before Meal** marker blinks.



Example: If you scroll down to **After Meal**, the **After Meal** marker blinks.

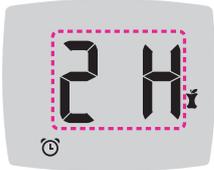


- When the **Meal Marker** you want is blinking, press the **OK** button.
- If this is a **Before Meal** reading, you can set a **Reminder** to test your blood glucose later. See the next section, *Set a Reminder*.

If you do not make a **Meal Marker** selection within 3 minutes, the meter turns off. Your blood glucose reading is stored in the **Logbook** without a **Meal Marker**.

Set a Reminder

- Make sure the **Reminder**  feature is On in **Settings**.
See *Set Reminder Feature* on page 45.
- Mark a blood glucose reading as a **Before Meal** reading, then press the **OK** button.



- To scroll from 2 hours to 0.5 hours by half-hour intervals, press the **▲** or **▼** button.

- To set the **Reminder**, press the **OK** button.



The screen returns to the **Before Meal** reading. The **Reminder** symbol  displays to confirm the Reminder is set.

Blood glucose test is complete.

smartLIGHT target range indicator

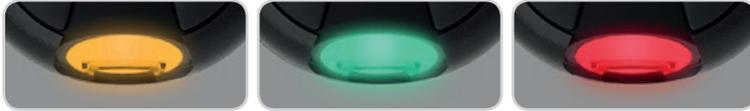
When your blood glucose test is complete, the meter displays your result with the units, time, date, meal marker (if selected), and target range symbol: Above Target , In Target , or Below Target .

Example: Blood test result with **Meal Marker** selected and a **Reminder** set:



If the **smartLIGHT** target range indicator is On, the test strip port displays a colour representing your result value compared to your **Before Meal**, **After Meal**, or **Overall Target Range**.

If you do not select a **Meal Marker**, your blood glucose test result is compared to an **Overall Target Range**.



**Above
Target Range** ↑

**In
Target Range** ✓

**Below
Target Range** ↓

If your blood glucose result is below target, the **smartLIGHT** target range indicator is red and the meter beeps twice.

NOTE: To change an Individual Target Range, see *Change Individual Target Ranges* on page 47. To change the Overall Target Range, see *Change Overall Target Range* on page 46.



To move to the **Home** screen, press the **OK** button

or



To turn the meter off, remove the test strip.

Test Results

⚠ WARNING

- Always consult your health care professional before changing your medication based on test results.
- If your blood glucose reading is under the critical level you have established with your health care professional, follow their advice immediately.
- If your blood glucose reading is over the recommended limit set by your health care professional:
 1. Wash and dry your hands well.
 2. Retest with a new strip.

If you get a similar result, follow your health care professional's advice immediately.

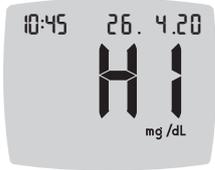
Expected Test Result Values

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations should be less than 100 mg/dL in the fasting state and less than 140 mg/dL in the post-prandial state (after a meal).⁴ You should consult with your health care professional for glucose values specific to your needs.

LO or HI Results



- If the meter beeps twice and displays the **LO** screen, your blood glucose reading is under 10 mg/dL. **Follow medical advice immediately.** Contact your health care professional.



- If the meter beeps once and displays the **HI** screen, your blood glucose reading is over 600 mg/dL:
 1. Wash and dry your hands well.
 2. Retest with a new strip.
 If results are still over 600 mg/dL, **follow medical advice immediately.**

Alternative Site Testing (AST): Palm



WARNING

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

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

For Alternative Site Testing, use the clear endcap. Your CONTOUR PLUS ELITE meter can be used for fingertip or palm testing. See the lancing device insert for detailed instructions on Alternative Site Testing.

Do not use AST under the following conditions:

- If you think your blood glucose is low.
- When blood glucose is changing rapidly, such as after a meal, after an insulin dose, or during or after exercise.
- If you are unable to feel symptoms of low blood glucose (hypoglycaemic unawareness).
- If you get alternative site blood glucose results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.

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 alternative 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 lancing device endcap to perform AST, contact Customer Service. See the back cover for contact information.

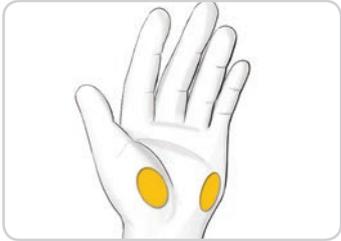
Get a Blood Drop: Alternative Site Testing



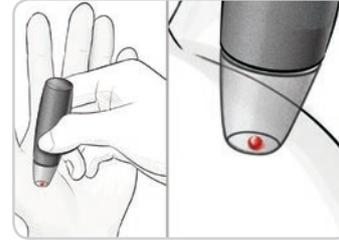
1. Wash your hands and the puncture site with antibacterial soap and warm water. Rinse and dry well.
2. Attach the clear AST endcap to the lancing device, if provided with your kit.

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, then press the release button.
5. Maintain steady pressure until a small, round blood drop forms.



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



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

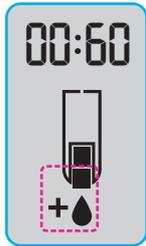
Immediately touch the tip of the test strip to the drop of blood. The blood is drawn into the test strip through the tip.

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

- Smears 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.

CAUTION: Do not press the test strip tip against the skin or place the blood on top of the test strip. These actions could lead to inaccurate results or errors.

Second-Chance sampling for AST—Apply More Blood



1. If the meter beeps twice and the screen displays a blinking blood drop with a plus sign, the test strip does not have enough blood.
2. Apply more blood to the **same** test strip within 60 seconds.

NOTE: If the screen displays an **E 1** error message, remove the strip and start with a new strip.

If the **Meal Marker** feature is On, the meter suggests a **Fasting** 🍷, **Before Meal** 🍏, **After Meal** 🍷, or **No Mark** ✕ marker for your blood glucose result. This is based on the time of day and the meal period: fasting/breakfast, lunch, dinner or overnight. The **Meal Marker** is blinking.



Do not press the OK button yet. You can select the blinking marker or choose a different **Meal Marker**.



3. If the blinking **Meal Marker** is the one you want, press the **OK** button

or

4. To select another **Meal Marker**, press the ▲ or ▼ button to scroll between markers.

Meal Marker choices if Meal Marker feature is On

Symbol	What the Symbol Means	Related Target Range
	Fasting: Use the Fasting marker when testing blood glucose levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	Before Meal Target Range
	Before Meal: Use the Before Meal marker when testing blood glucose levels within 1 hour before a meal.	
	After Meal: Use the After Meal marker when testing blood glucose levels within 2 hours after the first bite of a meal.	After Meal Target Range
	No Mark Selected: Use the No Mark symbol when testing at times other than after fasting or before or after a meal.	Overall Target Range

5. When the **Meal Marker** you want is blinking, press the **OK** button. To set a Reminder to test your blood after a meal, see *Set a Reminder* on page 20.
For more information about **Meal Markers**, see *Select a Meal Marker* on page 18.

Eject and Dispose of the Used Lancet



1. Do not use your fingers to remove the lancet from the lancing device.
The lancing device usually 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: 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}
- All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.
- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

Control Solution



WARNING

Shake the control solution well before testing.



CAUTION: Use only CONTOUR PLUS control solution (Normal, Low, and High) with your CONTOUR PLUS ELITE blood glucose monitoring system. Using anything other than CONTOUR PLUS control solution 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.



WARNING

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



CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiry dates on your test materials.

Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your CONTOUR PLUS ELITE meter with control solution only when the temperature is 15°C–35°C.

Always use CONTOUR PLUS control solutions. Other brands could yield incorrect results. If you need help locating CONTOUR PLUS control solutions, contact Customer Service. See the back cover for contact information.

Control Solution Testing

1. Remove a CONTOUR PLUS test strip from the bottle.
2. Tightly close the bottle lid immediately after you remove the test strip.
3. Hold the test strip with the grey square end facing up.



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



The meter turns on, displaying a test strip with a flashing blood drop.

CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.



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.

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



The meter counts down for 5 seconds before the control test result displays on the meter. The meter automatically marks the result as a control test.

Control test results are not included in your meter **Logbook** or in blood glucose Averages. Control test results are not evaluated against any Target Ranges.



10. Compare your control test result with the range printed on the test strip bottle or on the bottom of the test strip box.
11. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your result 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 ELITE meter for blood glucose testing until you resolve the issue. Contact Customer Service. See the back cover for contact information.

Logbook

The **Logbook** contains blood glucose test results and Meal Markers that you have made to those test results. The **Logbook** holds up to 800 results. When the **Logbook** reaches the maximum, the oldest test result will be removed as a new test is completed and saved to the **Logbook**.

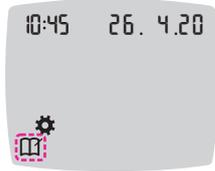
Review the Logbook

NOTE: To return to the **Home** screen while viewing the **Logbook**, press the **OK** button.

To review entries in the **Logbook**:

1. Press and hold the **OK** button until the meter turns on, about 3 seconds.

The **Logbook**  is blinking.



2. To select the blinking **Logbook**  symbol, press the **OK** button.
3. To view your individual test results in the **Logbook**, press the **▼** button.



4. To scroll through your test results, press the **▲** or **▼** button.
To scroll faster, press and hold the **▲** or **▼** button.



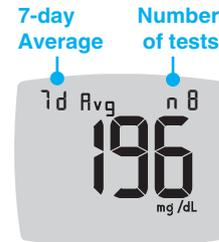
If you scroll past the oldest entry, the meter displays the **End** screen.

If you see a **LO** or **HI** test result, go to *LO or HI Results* on page 24 for more information.

5. To go back to the beginning to review entries, press the **OK** button to go to the **Home** screen, then select the **Logbook**  symbol.

View Averages

1. To enter the **Logbook** from the Home screen, press the **OK** button while the **Logbook**  is blinking.
2. To view your Averages, press the **▲** button from the *first Logbook* screen.



3. To scroll through your 7-, 14-, 30-, and 90-day Averages, press the **▲** button.
4. To return to your Logbook readings, press the **▼** button on the **7 d Avg** (7-day Average).
5. To exit Averages and return to the **Home** screen at any time, press the **OK** button.

Settings

In **Settings** you can:

- Change the time format.
- Change the time.
- Change the date format.
- Change the date.
- Turn **Sound** On or Off.
- Turn **Meal Markers** On or Off.
- Turn **Reminder** feature On or Off.
- View and change **Target Ranges**.
- Turn **smartLIGHT** feature On or Off.
- Turn **Bluetooth** wireless functionality On or Off.

You must accept or change each setting with the **OK** button.

Access Settings



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

The **Home** screen has 2 options: **Logbook**  and **Settings** .



2. To highlight the **Settings** symbol , press the **▼** button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the **▲** or **▼** button to navigate to the setting you want to change.
5. Press the **OK** button when the setting you want to change is blinking.



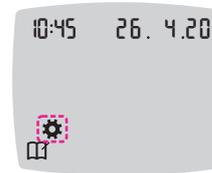
6. To exit from the **Settings** menu and return to the **Home** screen, press the **▲** or **▼** button until the **Settings** symbol  is blinking.
7. Press the **OK** button.

NOTE: If you are in a setting such as Date and you need to exit, press the **OK** button repeatedly until you get back to the **Home** screen.

Change the Time

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

The **Home** screen has 2 options: **Logbook**  and **Settings** .

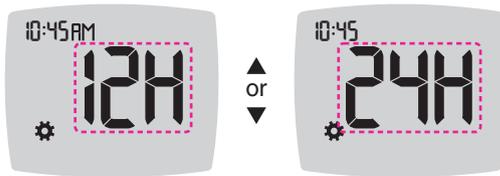


2. To highlight the **Settings** symbol , press the **▼** button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.



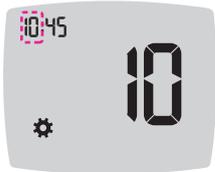
4. Press the **OK** button when the current time is blinking on the **Settings** screen. The time format is blinking.

5. To change the time format, if needed, press the ▲ or ▼ button, then press the **OK** button.



Time Format

The hour is blinking.



6. To change the hour, press the ▲ or ▼ button, then press the **OK** button.

The minutes are blinking.



7. To change minutes, press the ▲ or ▼ button, then press the **OK** button.

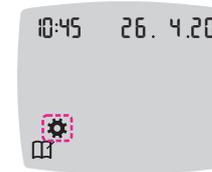
8. For a 12-hour time format, select **AM** or **PM**, as needed, then press the **OK** button.

The meter returns to the **Home** screen.

Change the Date

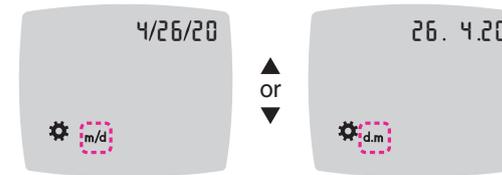
1. Press and hold the **OK** button until the meter turns on.

The **Home** screen has 2 options: **Logbook**  and **Settings** .



2. To highlight the **Settings** symbol , press the ▼ button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the ▼ button until the current date is blinking on the **Settings** screen, then press the **OK** button.



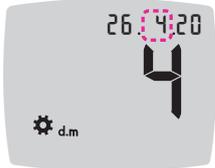
Date Format

The date format (**m/d** or **d.m**) is blinking.

5. To select **Month/Day/Year (m/d)** or **Day.Month.Year (d.m)**, press the ▲ or ▼ button, then press the **OK** button.



6. To change the year (blinking), press the ▲ or ▼ button, then press the **OK** button.



7. To change the month (blinking), press the ▲ or ▼ button, then press the **OK** button.



8. To change the day (blinking), press the ▲ or ▼ button, then press the **OK** button.

The meter returns to the **Home** screen.

Set the Sound

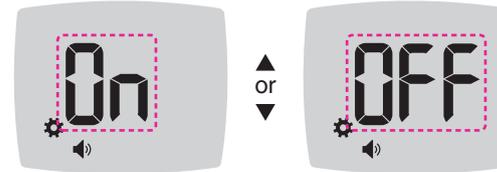
1. Press and hold the **OK** button until the meter turns on.

The **Home** screen has 2 options: **Logbook**  and **Settings** .



2. To highlight the **Settings** symbol , press the ▼ button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the ▼ button repeatedly until the **Sound** symbol  is blinking on the **Settings** screen, then press the **OK** button.



Sound Symbol: 

Your meter comes with the **Sound** turned On. Certain error messages override any **Sound** setting.

When **Sound** is On:

- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

5. To turn the **Sound** On or Off, press the ▲ or ▼ button to display the option you want.
6. Press the **OK** button.

NOTE: Some sounds remain On even when you turn the **Sound** feature Off. To turn sounds Off for a below-target blood glucose reading, turn the **smartLIGHT** feature to Off.

The meter returns to the **Home** screen.

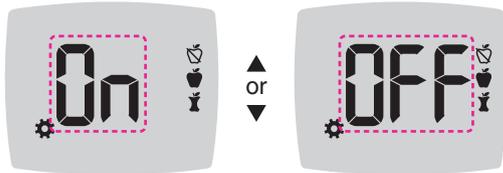
Set Meal Markers

1. Press and hold the **OK** button until the meter turns on.
The **Home** screen has 2 options: **Logbook**  and **Settings** .



2. To highlight the **Settings** symbol , press the **▼** button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the **▼** button repeatedly until the **Meal Marker** symbols    are blinking, then press the **OK** button.



Meal Marker Symbols:   

Your meter comes with the **Meal Marker** feature turned Off.

5. To turn **Meal Markers** On or Off, press the **▲** or **▼** button to display the option you want.
6. Press the **OK** button. The meter returns to the **Home** screen.

NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see *Set Meal Markers* on page 44.

1. Press and hold the **OK** button until the meter turns on.
The **Home** screen has 2 options: **Logbook**  and **Settings** .

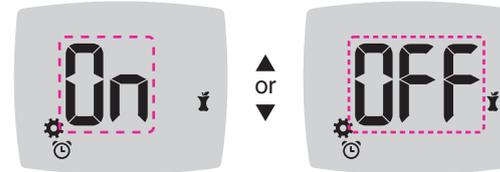


2. To highlight the **Settings** symbol , press the **▼** button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the **▼** button repeatedly until the **Reminder** symbol  is blinking, then press the **OK** button.

Your meter comes with the **Reminder** feature turned Off.

5. To turn the **Reminder** feature On or Off, press the **▲** or **▼** button to display the option you want.



Reminder Symbol: 

6. Press the **OK** button. The meter returns to the **Home** screen.

Change Overall Target Range



WARNING

Discuss your Target Range settings with your health care professional.

When the **Meal Marker** feature is Off, your meter provides a pre-set **Overall Target Range**. A Target Range has a low limit and a high limit, such as 70 mg/dL–180 mg/dL. You may want your blood glucose readings to stay within a target range. You can change the **Overall Target Range** in **Settings**.

1. Press and hold the **OK** button until the meter turns on.
The **Home** screen has 2 options: **Logbook**  and **Settings** .

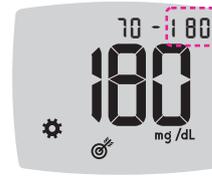


2. To highlight the **Settings** symbol , press the **▼** button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the **▼** button repeatedly until the **Target** symbol  is blinking, then press the **OK** button. The meter displays the **Overall Low Target** screen.



5. To change the blinking **Low** end of the **Overall Target Range**, press the **▲** or **▼** button.
6. To set the **Low** end, press the **OK** button.



7. To change the blinking **High** end of the **Overall Target Range**, press the **▲** or **▼** button.
8. To set the **High** end, press the **OK** button.

The meter returns to the **Home** screen.

Change Individual Target Ranges



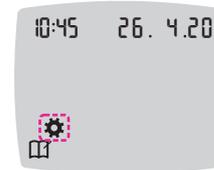
WARNING

Discuss your Target Range settings with your health care professional.

When the **Meal Marker** feature is On, you have 2 Target Ranges on your meter: a **Before Meal Target Range**  (which is the same as Fasting) and an **After Meal Target Range** . When the **Meal Marker** feature is Off, there is only 1 **Overall Target Range**.

You can change these ranges in **Settings** in your meter and in the **CONTOUR®DIABETES** app.

1. Press and hold the **OK** button until the meter turns on.
The **Home** screen has 2 options: **Logbook**  and **Settings** .



2. To highlight the **Settings** symbol , press the **▼** button.
3. When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

4. Press the **▼** button repeatedly until the **Target** symbol  is blinking, then press the **OK** button. The meter displays the **Low Target** screen.

NOTE: There is only *one* Low target number for both the **Before Meal** 🍏 and **After Meal** 🍷 Target Ranges.

Change Low for Both Target Ranges



- To change the blinking **Low** for both **Target Ranges** (**Before Meal** 🍏, **After Meal** 🍷), press the ▲ or ▼ button.
- To set the **Low** end of both **Target Ranges**, press the **OK** button.
The meter displays the **Before Meal High Target** screen.

Change Before Meal Target Range



- To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
- To set the **High** end, press the **OK** button.
The meter displays the **After Meal High Target** screen.

NOTE: The **Before Meal Target Range** is also the Target Range for a blood glucose reading marked as **Fasting**.

Change After Meal Target Range



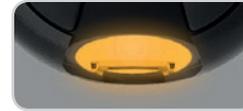
- To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
- To set the **High** end, press the **OK** button.

The meter returns to the **Home** screen.

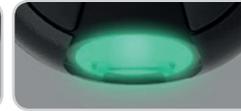
Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** feature turned On.

When the **smartLIGHT** target range indicator is On, the test strip port displays a colour that indicates if your reading is above, in, or below your personal Target Range.



Above Target Range ▲



In Target Range ✓



Below Target Range ▼

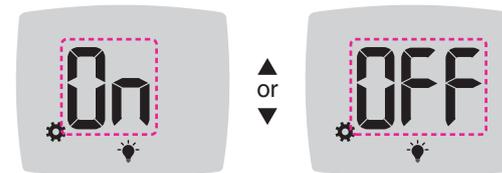
- Press and hold the **OK** button until the meter turns on.

The **Home** screen has 2 options: **Logbook** 📖 and **Settings** ⚙️.



- To highlight the **Settings** symbol ⚙️, press the ▼ button.
- When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

- Press the ▼ button repeatedly until the **smartLIGHT** symbol 💡 is blinking, then press the **OK** button.



smartLIGHT Symbol: 💡

- To turn the **smartLIGHT** feature On or Off, press the ▲ or ▼ button to display the option you want.
- Press the **OK** button.

Set Bluetooth Wireless Functionality

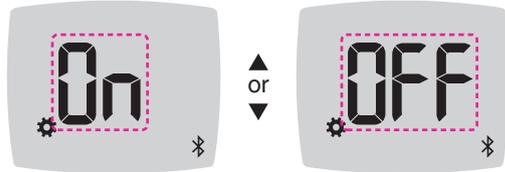
After pairing your meter with a mobile device, the **Bluetooth** setting can be turned On or Off. For pairing instructions, see page 52.

- Press and hold the **OK** button until the meter turns on.
The **Home** screen has 2 options: **Logbook**  and **Settings** .



- To highlight the **Settings** symbol , press the ▼ button.
- When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

- Press the ▼ button repeatedly until the **Bluetooth** symbol  is blinking, then press the **OK** button.



Bluetooth Symbol: 

- To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button to display the option you want.
- Press the **OK** button.

The meter returns to the **Home** screen.

The CONTOUR DIABETES app for Your CONTOUR PLUS ELITE meter

Your CONTOUR PLUS ELITE meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet. You can do the following things with your CONTOUR DIABETES app:

- Add Notes after testing that help to explain your results:
 - List meals containing carbs.
 - Note changes in medication.
 - Add photos of your meal.
 - Log an increase or decrease in activity.
 - Set testing reminders.
 - Access easy-to-read graphs of test results over a day or over a period of time.
 - Share reports.
 - Discreetly view information.
 - Review your **Fasting**, **Before Meal**, **After Meal**, and **View All** results on a daily graph.
 - Change meter settings, as necessary.
- The CONTOUR DIABETES app does these things for you:
- Automatically displays your results.
 - Saves your Notes in **My Readings**.
 - Displays your trends and test results as they compare with your targets.
 - Offers quick and valuable tips to help you manage your diabetes.

When your CONTOUR PLUS ELITE meter is paired with the CONTOUR DIABETES app:

- You can set or change a **Meal Marker** in the meter **Logbook** from the app.
- The app will always sync your most recent Target Range from the app or meter, across the system.
- The app date and time can sync to your meter.
- You can manage your meter settings from the app, like Sound or smartLIGHT target range indicator.

Download the CONTOUR DIABETES app

1. On your compatible smartphone or tablet, go to the App StoreSM or the Google PlayTM store.
2. Search for the CONTOUR DIABETES app.
3. Install the CONTOUR DIABETES app.

Pairing Mode

CAUTION: There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood glucose readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

To pair your meter with the CONTOUR DIABETES app, download the app and follow the instructions to *Pair a Meter*.

To put your meter in pairing mode:

1. If your meter is off, press and HOLD the **OK** button until the meter turns on. The **Home** screen displays.



2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in Step 3). A blue light blinks when you are in pairing mode.

3. When the meter serial number displays, follow the instructions on the app to match the meter serial number.



Meter serial number

Example: Your meter in pairing mode.



Pass code

When a connection is made, the meter displays the 6-digit pass code you need to enter on the smart device.



When you have successfully paired your meter with the CONTOUR DIABETES app, the meter's blue light and the **Bluetooth** symbol display.

The meter returns to the **Home** screen.

NOTE: You can update your Target Ranges from the meter or from the app. The most recently changed Target Ranges will update in the meter and the app when they are synced.

Meter Care

Caring for your meter:

- Store the 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 your meter and test strips to excessive humidity, heat, cold, dust, or dirt.

CAUTION: Do not allow cleaning solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports, such as the USB port.

1. Clean the exterior of the meter using a moist (not wet) lint-free tissue with soapy water or disinfect for 1 minute using a disinfectant solution made of 1 part bleach mixed with 9 parts water.
2. Wipe dry with lint-free tissue after cleaning.
3. Do not insert anything into the test strip port or attempt to clean inside the test strip port.

Transfer Results to the CONTOUR DIABETES app

CAUTION: The CONTOUR PLUS ELITE meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any erroneous results from the use of other software.

You can automatically transfer results from your CONTOUR PLUS ELITE meter wirelessly to your compatible smartphone or tablet. See *Download the CONTOUR DIABETES app* on page 52 and follow the app instructions to pair your meter and get started.

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the CONTOUR PLUS ELITE meter is connected to a computer.

You can transfer test results from the CONTOUR PLUS ELITE meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need diabetes management software and a 1-metre (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores.



Ensure your meter's USB port door is completely closed when not in use.

CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

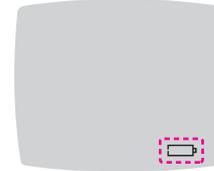
Batteries

When the batteries are low, the **Low Batteries** symbol displays on every screen.

Replace the batteries immediately. When you see this symbol, you can only test about 10 more times at a frequency of 3 tests per day before the batteries are dead.



The meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.



When you are no longer able to perform a test due to low batteries, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries



1. Before replacing your batteries, turn off your meter.
2. Turn the meter over and slide the battery cover in the direction of the arrow.

- Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.

NOTE: Always check the date and time after you replace the batteries.



- Make sure the '+' sign is facing up on the new batteries.
- Press each battery into a compartment.

- Slide the battery cover back into place.
- Discard batteries according to your local environmental regulations.

⚠ WARNING

Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

Error Detection Displays

The meter screen displays error codes (E plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press the **OK** button to turn off the meter.

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

Error Code	What It Means	What to Do
Strip Errors		
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E 3	Strip Upside Down	Remove the strip and insert it correctly.
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR PLUS test strip.
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E 8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.

Error Code	What It Means	What to Do
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a cooler area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E30–E99	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

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

Customer Service Checklist

When speaking with the Customer Service representative:



1. Have your CONTOUR PLUS ELITE blood glucose meter, CONTOUR PLUS test strips, and CONTOUR PLUS control solution available when you call.
2. Locate the model number (A) and serial number (B) on the back of the meter.

3. Locate the test strips' expiry date on the bottle.
4. 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 CR2032 or DL2032 coin cell batteries.
- CONTOUR PLUS ELITE user guide.
- CONTOUR PLUS ELITE quick reference guide.
- CONTOUR PLUS test strips.
- CONTOUR PLUS normal control solution.
- CONTOUR PLUS low control solution.
- CONTOUR PLUS high control solution.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

Technical Information: Accuracy

The CONTOUR PLUS ELITE blood glucose monitoring system was tested with capillary blood samples from 100 subjects. 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 following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 100 mg/dL

Difference range in values between YSI laboratory reference method and CONTOUR PLUS ELITE meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Number (and percent) of samples within specified range	154 of 174 (88.5%)	174 of 174 (100%)	174 of 174 (100%)

Table 2: System accuracy results for glucose concentration ≥ 100 mg/dL

Difference range in values between YSI laboratory reference method and CONTOUR PLUS ELITE meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	350 of 426 (82.2%)	425 of 426 (99.8%)	426 of 426 (100%)

Table 3: System accuracy results for glucose concentrations from 21 mg/dL to 521 mg/dL

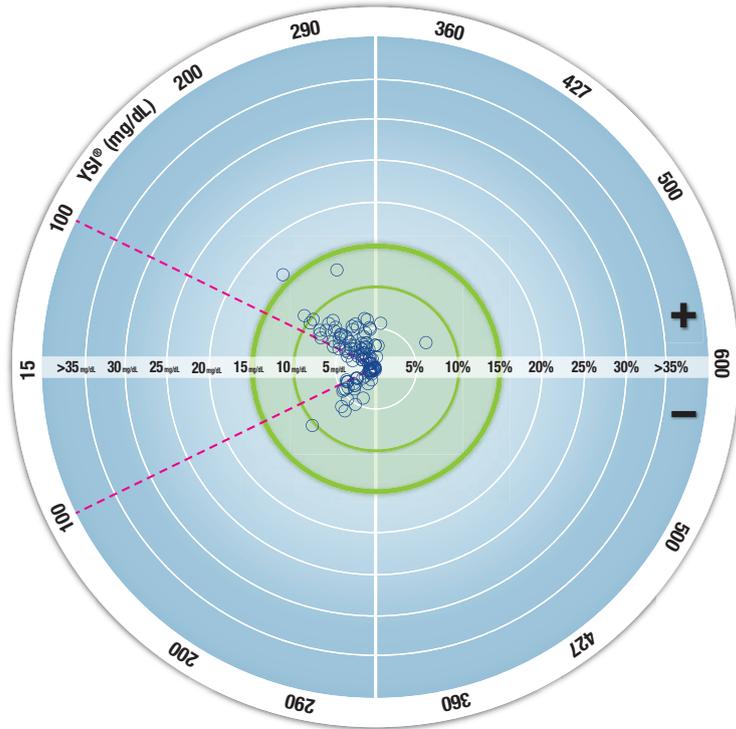
Within ± 15 mg/dL or ± 15%
600 of 600 (100%)

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either ± 15 mg/dL of the average measured values of the reference measurement procedure at glucose concentrations < 100 mg/dL or within ± 15% at glucose concentrations ≥ 100 mg/dL.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 128 lay persons showed the following results: 100% within ± 15 mg/dL of the medical laboratory values at glucose concentrations < 100 mg/dL and 99.1% within ± 15% of the medical laboratory glucose concentrations ≥ 100 mg/dL.

User Accuracy Radar Plot



○ All samples (n = 128) — 10 mg/dL or 10% — 15 mg/dL or 15%

The 128 data points represent the blood glucose monitoring system (BGMS) results. The distance from the centre represents the magnitude of the error compared with the laboratory reference result.

If a data point is at the centre, there is zero error, which means the BGMS reading is identical to the laboratory value.

The data points inside the bold green outer circle represent readings within ± 15 mg/dL for values < 100 mg/dL or $\pm 15\%$ error for values ≥ 100 mg/dL versus laboratory reference to demonstrate how the BGMS compares to the ISO 15197:2013 accuracy requirements.

Technical Information: Precision

A measurement repeatability study was conducted with the CONTOUR PLUS ELITE blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 39 mg/dL to 348 mg/dL. With each blood specimen, each of 3 lots of CONTOUR PLUS test strips was tested 10 times on each of 10 instruments for a total of 300 readings. The following precision results were obtained.

Table 1: System repeatability results for CONTOUR PLUS ELITE meter using CONTOUR PLUS test strips

Mean, mg/dL	Pooled Standard Deviation, mg/dL	95% CI of SD, mg/dL	Coefficient of Variation, %
41.0	1.1	1.04–1.24	2.8
79.2	1.1	0.98–1.16	1.3
140.0	1.9	1.72–2.03	1.3
216.1	2.5	2.34–2.77	1.2
347.5	4.4	4.03–4.78	1.3

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 3 glucose levels. With each control solution, each of 3 lots of CONTOUR PLUS test strips was tested once on each of 10 instruments on 10 separate days for a total of 300 readings. The following precision results were obtained.

Table 2: System intermediate precision results for CONTOUR PLUS ELITE meter using CONTOUR PLUS test strips

Control Level	Mean, mg/dL	Pooled Standard Deviation, mg/dL	95% CI of SD, mg/dL	Coefficient of Variation, %
Low	42.9	0.6	0.52–0.62	1.3
Normal	127.8	1.4	1.32–1.56	1.1
High	374.1	4.7	4.30–5.10	1.2

Specifications

Test Sample: Capillary and venous whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 10 mg/dL–600 mg/dL of glucose in blood

Countdown Time: 5 seconds

Memory: Stores most recent 800 test results

Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity

Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)

Meter Storage Temperature Range: -20°C



Meter Operating Temperature Range: 5°C



Control Testing Temperature Range: 15°C



Meter Operating Humidity Range: 10% RH–93% RH

Test Strip Storage Conditions: 0°C–30°C, 10%–80% Relative Humidity (RH)

Dimensions: 78.5 mm (L) x 56 mm (W) x 18 mm (H)

Weight: 53 grams

Meter Life: 5 years with normal use in accordance with instructions

Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm

Radio Frequency Technology: Bluetooth Low Energy

Radio Frequency Band: 2.4 GHz–2.483 GHz

Maximum Radio Transmitter Power: 1 mW

Modulation: Gaussian Frequency Shift Keying (GFSK)

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

Hereby, Ascensia Diabetes Care declares that the radio equipment type Blood Glucose Meter is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:

www.diabetes.ascensia.com/declarationofconformity

Product Labeling Symbols

The following symbols are used throughout the product labeling for the CONTOUR PLUS ELITE blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

Symbol	What It Means
	Use by date (last day of the month)
	Warning, improper use could result in injury or illness.
	Do not reuse
	Sterilized using irradiation
	Batch Code
	Control Discard Date
	Temperature limitations
	Consult instructions for use
	In Vitro Diagnostic Medical Device
	Manufacturer
	Catalogue number
	Control Range Low
	Control Range Normal
	Control Range High

Symbol	What It Means
	Shake 15 times
	Number of test strips included
	<p>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.</p> <p>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.</p> <p>Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.</p>

Principles of the Procedure: The CONTOUR PLUS ELITE 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 test 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 by the user is required.

Comparison Options: The CONTOUR PLUS ELITE system is designed for use with capillary and venous whole blood. Comparison with 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).⁷

References

1. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
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6. Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. US Department of Health and Human Services; update June 8, 2017. <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
7. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.

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 life from the date of original purchase (except as noted below). During the stated 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 ELITE 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 ELITE 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 ELITE 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 ELITE meter or test results when used with any software other than the CONTOUR DIABETES app (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.

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.

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For information on patents and related licenses, see **www.patents.ascensia.com**.

Purchase of this product does not alone confer a license to use under these patents. Such a license only arises, and extends only to, when the CONTOUR PLUS ELITE meters and CONTOUR PLUS test strips are used together. No test strip supplier other than the supplier of this product is authorized to grant such a license.

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