

# Contour<sup>®</sup> plus

Blood Glucose Monitoring System

To check meter online registration availability, visit  
[www.diabetes.ascensia.com/registration](http://www.diabetes.ascensia.com/registration)



Uses only CONTOUR<sup>®</sup>PLUS  
blood glucose test strips.

**USER GUIDE**

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## INTENDED USE

The CONTOUR PLUS blood glucose monitoring system, comprising the blood glucose meter, the compatible test strips, and control solutions, is an automated system intended for the quantitative measurement of glucose in:



- arterial blood
- venous blood
- fresh capillary whole blood drawn from the fingertip or palm
- fresh capillary whole blood drawn from the heel in neonates

The system is intended to be used for self-testing by persons with diabetes and for near-patient testing by health care professionals to monitor the effectiveness of diabetes control. The system is also intended for the quantitative measurement of glucose levels in neonates.

The CONTOUR PLUS blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly).

**The system is intended for in vitro diagnostic use only.**

## IMPORTANT SAFETY INFORMATION

-  Read your CONTOUR PLUS 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.
- Your CONTOUR PLUS meter works **ONLY** with CONTOUR PLUS test strips and CONTOUR PLUS control solution.
-  Health care professionals, see Section 4 *Technical, Service & Care: Health Care Professionals*.

## WARNING

- If your blood glucose reading is **under** the 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.

- If you are experiencing symptoms of high or low blood glucose, test your blood glucose. If your test result is under the level you have established with your health care professional or over the recommended limit, 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.<sup>1-3</sup>
- **Talk to Your Health Care Professional:**
  - Before changing HI or LO settings in your meter.
  - Before changing your medication based on test results.
  - About whether Alternative Site Testing (AST) is appropriate for you.
  - Before making any other decision of medical relevance.
- Do not use results from alternative site samples to calibrate a continuous glucose monitoring device or for insulin dose calculations.

- Discuss the HI and LO settings in your meter with your health care professional.
- Do not calibrate a continuous glucose monitoring device from a control result.
- Do not calculate an insulin dose based on a control result.
- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.), may cause damaging electrostatic discharges that may cause erroneous results.
- Do not use this instrument in proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
- This equipment is designed for use in a home health care environment and in a professional health care facility environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of interference.

### **Potential Biohazard**

- Always wash your hands with 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 for the prevention of blood-borne transmissible diseases.
- 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.

- Health care professionals should follow the biohazard disposal requirements for their facility.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.<sup>4,5</sup>
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.<sup>4</sup> See Section 4 *Technical, Service & Care: Cleaning and Disinfection*.
- For complete instructions on cleaning and disinfecting your meter, see Section 4 *Technical, Service & Care: Cleaning and Disinfection*.
-  Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.
- 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.<sup>4,5</sup>

### **Small Parts**

- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.

### **CAUTION**

- Use only CONTOUR PLUS control solution (Normal, Low, and High) with your CONTOUR PLUS blood glucose monitoring system. Using anything other than CONTOUR PLUS control solution can cause inaccurate results.

- 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.
- Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.
- 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.
- Do not allow cleaning or disinfectant solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports.

## 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%.
- **Preservatives:** Blood may be collected by health care professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.



- **Health Care Professionals:** Venous, arterial and neonatal blood testing is limited to health care professional use.
- **Alternative Site Testing (AST):** Do not use results from alternative site samples to calibrate a continuous glucose monitoring device or for insulin dose calculations.

## NOTES

- Always keep the CONTOUR PLUS test strips in their original bottle or foil packet. 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 or foil packet can damage your test strips. This could lead to inaccurate results.
- Examine the product for missing, damaged, or broken parts. If the test strip packaging is open or damaged, do not use those test strips. For replacement parts, contact Customer Service. See *Contact Information* or the carton.
- 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.
- A summary of safety and performance (SSP) of your device is available at: <https://ec.europa.eu/tools/eudamed>  
Use the following information:  
Manufacturer name: Ascensia Diabetes Care Holdings AG  
Device name: Contour Plus blood glucose meter

- 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 have a decimal point;
  - Results in mg/dL do not have a decimal point.

Example: **5.2** mmol/L or **93** mg/dL

Check your display screen to be sure the results are shown correctly. If not, contact Customer Service. See *Contact Information*.
- The CONTOUR PLUS blood glucose monitoring system has a measuring range of 0,6 mmol/L to 33,3 mmol/L (10 mg/dL to 600 mg/dL).
  - For results under 0,6 mmol/L (10 mg/dL) or over 33,3 mmol/L (600 mg/dL):
    - If your meter does not display a value and displays the flashing “**L 0**” screen, **contact your health care professional immediately.**
    - If your meter does not display a value and displays the flashing “**H i**” screen, wash your hands or the test site and repeat the test with a new strip. If the meter again displays the flashing **HI** screen, **follow medical advice immediately.**
- If a serious incident has occurred during the use of this device or as a result of its use, please report it to the manufacturer and/or its authorized representative and to your national authority.

## 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.

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

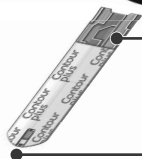
## Your CONTOUR PLUS meter



## 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 Section 3 *Setup and Use: Setting the Time, Date and Sound*.

## Your CONTOUR PLUS test strip



### Grey End

Insert this end into the test strip port

### Sample Tip










Blood sample pulled in here

## 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 **0.0.0** is fully displayed. If there are missing segments, see *Section 4 Technical, Service & Care: Error Codes and Symbols*. This may affect the way you see your results.

Icon	What It Means
88/88	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.
888	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.
A	Indicates Average.
mmol 7dL	Results are displayed as mmol/L or mg/dL. The 7 appears when viewing 7 day HI-LO summary.
d.m/d	Day/month format.
	The batteries are low and need to be changed, and will remain on display until batteries are changed.
AM PM	Appear 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 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 packaging is open or damaged, do not use those test strips. For replacement parts, contact Customer Service. See *Contact Information*.

**NOTE:** 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, and 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. See Section 4 *Technical, Service & Care: Customer Service Checklist*.


### **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.<sup>4</sup> See Section 4 *Technical, Service & Care: Cleaning and Disinfection*.
- Always wash your hands with 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 and disinfecting your meter, see Section 4 *Technical, Service & Care: Cleaning and Disinfection*.

## **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.**

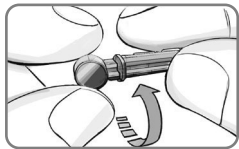
### **WARNING: Potential Biohazard**

- The lancing device provided 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.
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
- Health care professionals should follow the biohazard disposal requirements for their facility.

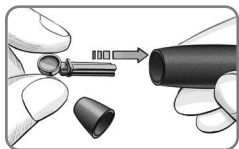


For Alternative Site Testing instructions, see Section 2 *Testing: Alternative Site Testing (AST) – Palm*.

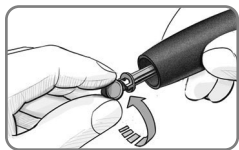
1. Remove the endcap from the lancing device.



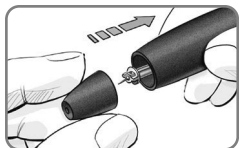
2. Loosen the round protective cap on a lancet by rotating it  $\frac{1}{4}$  turn, but do not remove it.



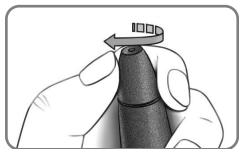
3. Insert the lancet firmly into the lancing device until it comes to a full stop.



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

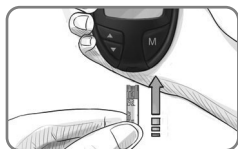
**CAUTION:** Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

**NOTE:** If strips are stored in a bottle, tightly close the bottle lid immediately after you remove the test strip.

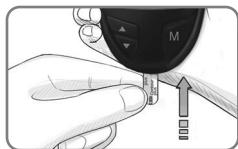
Some supplies are not available in every region.



1. Remove a CONTOUR PLUS test strip.



2. Hold the test strip with the grey end facing up toward the meter.



3. Insert the grey 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.

**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.

## Getting the Blood Drop – Fingertip Testing

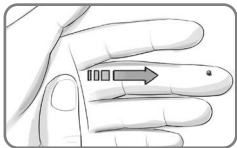
**NOTE:** For information on Alternative Site Testing, see Section 2 *Testing: Alternative Site Testing (AST) – Palm*.

### WARNING

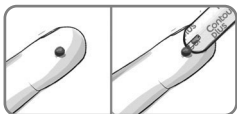
Residue on your hands (for example, foods or sanitizing gels) may affect your test results. Always wash your hands with soap and water, and dry them well before and after testing or handling the meter, lancing device, or test strips.



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



2. Stroke your hand and finger 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



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.**

Fingertip testing



**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.



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

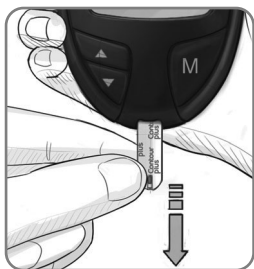


You have about 30 seconds to apply more blood to the same strip. If you are not able to apply enough blood within that time, an **E 2** error code will be displayed. Dispose of the used test strip as medical waste or as advised by your health care professional and start over with a new strip.



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 (L-2) settings** in **Section 3 Setup and Use**. 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.

## 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 5,6 mmol/L in the fasting state and less than 7,8 mmol/L in the postprandial state (after a meal).<sup>6</sup> You should consult with your health care professional for glucose values specific to your needs.

### WARNING

- Always consult your health care professional before changing your medication based on test results.
- **If your blood glucose reading is under the 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.

## Alternative Site Testing (AST) – Palm

### WARNING

- **Ask your health care professional if Alternative Site Testing (AST) is right for you.**
- **Do not use results from alternative site samples to calibrate a continuous glucose monitoring device or for insulin dose calculations.**

For Alternative Site Testing, use the clear endcap. Your CONTOUR PLUS 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 (after a meal, insulin dose or 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 endcap to perform AST, contact Customer Service. See *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.**

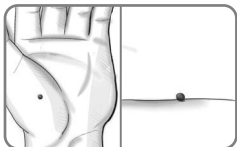


3. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones and tendons.



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.



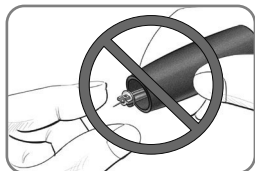
If the first blood drop is not enough, the meter may beep twice and display a strip underfill screen image  .



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.

See Section 2 *Testing: Expected Test Result Values*.


## 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: 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.<sup>4,5</sup>
- 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 for the prevention of bloodborne transmissible 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 soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

## Control Solution Testing

**NOTE:** Shake the control solution well before testing.



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

**You should perform a control test when:**

- You think your test strips may be damaged.
- You think your meter may not be working properly.
- You have repeated, unexpected blood glucose results.

Health care professionals should follow quality control testing requirements established by their facility.

## WARNING

- **Unmixed control solution may cause inaccurate results.**
- **Do not calibrate a continuous glucose monitoring device from a control result.**
- **Do not calculate an insulin dose based on a control result.**
- **Control solutions are not to be swallowed.**

Some supplies are not available in every region.



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

### Refer to your control solution insert.

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. Store control solutions between 9°C and 30°C.

Contact Customer Service to obtain control solution. See *Contact Information*.

**NOTE:** Tightly close the bottle lid immediately after you remove the test strip.

1. Remove a test strip from the bottle or foil packet.



2. Hold the test strip with the grey end facing up.
3. Insert the grey 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.

**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.

**NOTE:** 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.



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.

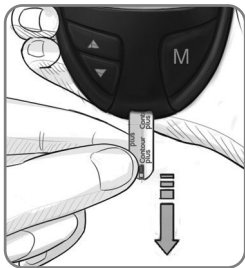
**NOTE:** The ✓ does not indicate the control test result is within the specified range. It only marks it as a control solution test. It will not be included in your averages.

- 11.** Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.



If the result you get does not fall within the range listed on the test strip bottle label or foil packet, 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 *Contact Information*.



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

# 3

## SETUP AND USE

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

## Setup 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

## BASIC MODE (L-1)



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.

## ADVANCED MODE (L-2)



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 Setup



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 setup 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.



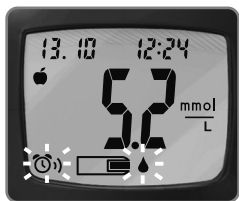
If you want to set the reminder, press **M**. The 🕒 will appear and stop flashing.

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 (see Section 2 *Testing*).





When you have completed this test and the result is shown on the display,  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 .

Press **▲** or **▼** 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
<b>Pre-Meal</b> Press ▲ or ▼	 (Flashing)	Press <b>M</b>		Result is marked as a pre-meal test. You can now set a reminder.
<b>Reminder</b> Press ▲ or ▼	 (Flashing)	Press <b>M</b>		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.
<b>Post-Meal</b> Press ▲ or ▼	 (Flashing)	Press <b>M</b>		Result is marked as a post-meal test.*
<b>Diary</b> Press ▲ or ▼	 (Flashing)	Press <b>M</b>		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.<sup>7</sup>

## Transferring Results to a Computer

You can transfer test results from the CONTOUR PLUS 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 data cable.

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

## 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.**
- **n̄ 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.

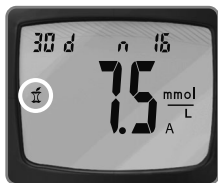


**Press ▲ to view the 30 day average.**

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 *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.
<b>E1</b> 	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.



What You See	What It Means	What You Should Do
<p><b>E2</b></p> 	<p>The test strip has not filled enough for an accurate test. Insufficient blood drop.</p>	<p>Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing.</p>
<p><b>E3</b></p> 	<ul style="list-style-type: none"> <li>• The meter is sensing a used test strip.</li> <li>• The wrong control solution was used.</li> </ul>	<ul style="list-style-type: none"> <li>• Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing.</li> <li>• If control testing, make sure to use CONTOUR PLUS control solution.</li> </ul>
<p><b>E4</b></p> 	<p>Test strip not inserted correctly.</p>	<p>Remove and reinsert the test strip properly (see Section 2 <i>Testing: Inserting the Test Strip</i>).</p>
<p><b>E5 E9</b> <b>E6 E12</b> <b>E8 E13</b></p>	<p>Potential software or hardware issue.</p>	<p>Remove the test strip and retest using a new test strip. If you continue to have problems, contact Customer Service. See <i>Contact Information</i>.</p>



What You See	What It Means	What You Should Do
<p><b>E7</b></p> 	<p>Incorrect test strip.</p>	<p>Remove the test strip and retest using a new test strip. Make certain that you are using a CONTOUR PLUS test strip.</p>
<p><b>E10</b></p>	<p>Invalid date or time.</p>	<p>This error occurs only in Communication mode. See <i>Section 3 Setup and Use: Setting the Time, Date and Sound</i> to reset the date or time. If you continue to see this error, please contact Customer Service. See <i>Contact Information</i>.</p>
<p><b>E11</b></p>	<p>Abnormal result.</p>	<p>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 CONTOUR PLUS test strips should be used.</p>

What You See	What It Means	What You Should Do
 <p>(When you only see “HI”)</p>	<p>Test result is above 33,3 mmol/L</p>	<ul style="list-style-type: none"> <li>• Wash and dry your hands well and the test site. Repeat the test using a new test strip.</li> <li>• If your result still flashes <b>HI</b>, follow medical advice immediately.</li> </ul>
 <p>(When you only see “LO”)</p>	<p>Test result is below 0,6 mmol/L</p>	<p>Contact your health care professional immediately.</p>
<p><b>Some display segments do not appear when the meter initially turns on.</b></p>	<p>Possible meter electronics failure.</p>	<p>Compare meter display with the illustration in Section 1 <i>Getting Started: Your Meter Display</i>. If the display is not correct, contact Customer Service. See <i>Contact Information</i>.</p>
<p><b>Results are not displayed in expected units of measure (mmol/L).</b></p>	<p>This may affect the way you see your results.</p>	<p>Contact Customer Service. See <i>Contact Information</i>.</p>

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

## Changing the Batteries

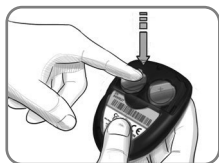


Batteries should be replaced when the meter continually displays  or the meter briefly shows  and then turns off (see **Section 4 Technical, Service & Care: Error Codes and Symbols**).



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

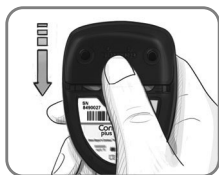
**NOTE:** If you put the new batteries in the meter within 5 minutes of taking the old ones out, all your settings and results will be saved. If you take more than 5 minutes, you will need to reset the date and time although your other settings and results will be saved.



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. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.**

## 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.

## Cleaning and Disinfection

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

**NOTE:** Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components.

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

Your CONTOUR PLUS meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage.

Call Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display.

### Self-Testing

It is recommended to clean and then disinfect your meter once a week.

**NOTE:** Do not insert anything into the test strip port or attempt to clean inside the test strip port.

1. The exterior of the meter may be cleaned using a moist (not wet) lint-free tissue with soapy water.

2. For disinfection, clean and then disinfect the meter for 1 minute using a solution made of 1 part bleach mixed with 9 parts water. Alternatively, commercially available wipes containing 0,55% sodium hypochlorite (bleach) may be used following the instructions provided with the wipes.
3. Dry the meter with lint-free tissue after cleaning and disinfection.

## Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility. The CONTOUR PLUS meter case components have been shown to be compatible (by soaking for 168 hours) with the following disinfectant solutions: 70% isopropyl alcohol, sodium hypochlorite (bleach), and didecyldimethylammonium chloride (DDAC).

## Technical Assistance

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system and contact Customer Service at **[www.diabetes.ascensia.com](http://www.diabetes.ascensia.com)** for assistance:

- Cloudy or damaged display,
- on/off button malfunction,
- or quality control results outside of the specified range.



# 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](http://www.diabetes.org)), 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 the 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.

## System Specifications

**Test Sample:** Venous, arterial or capillary whole blood

**Hematocrit:** 0% - 70%

**Test Result:** Referenced to plasma/serum glucose

**Sample Volume:** 0,6  $\mu$ L

**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 Storage Temperature Range:** -40°C - 65°C

**Meter Operating Temperature Range:** 5°C - 45°C

**Control Solution Operating Temperature Range:** 15°C - 35°C

**Meter Operating Humidity Range:** 10% RH - 93% RH

**Meter Storage Humidity Range:** 10% RH - 93% RH

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

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

**Weight:** 47,5 grams

**Meter Life:** 5 years (up to 6000 blood glucose tests)

**Sound Output:** 40 - 80 dBA

**Electromagnetic Compatibility (EMC):** The CONTOUR PLUS meter complies with the electromagnetic requirements specified in EN ISO 15197:2015. 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. The CONTOUR PLUS meter meets the requirements of IEC 61326-1 for radio frequency interference. See WARNING in *Important Safety Information* for additional information regarding electrostatic discharge safety.















**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).<sup>8</sup>

## 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
	Use by date (last day of month)
	Batch code
	Do not reuse
	Consult instructions for use
	In Vitro Diagnostic Medical Device
	Manufacturer
	Catalogue number
	Control Discard date
	Number of test strips included
	Keep dry
	Control Range Normal
	Control Range Low
	Control Range High
	Temperature limitations

Symbol	What It Means
	Sterilized using irradiation
	Caution
	Shake 15 times
	Biological risk
	Authorized representative in the European Community/European Union
	Unique device identifier (UDI)
	<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. Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.</p>
	<p>Recyclable material. Separate waste collection. Check your local municipal guidelines.</p> <ul style="list-style-type: none"> <li> High-density polyethylene</li> <li> Low-density polyethylene</li> <li> Other plastics</li> <li> Non-corrugated fiberboard (paperboard)</li> <li> Paper</li> </ul>

## 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 $\pm$ 0,28 mmol/L	Within $\pm$ 0,56 mmol/L	Within $\pm$ 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  $\geq 5,55$  mmol/L**

Difference range in values between YSI laboratory reference method and CONTOUR PLUS meter	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 0,83$ mmol/L or $\pm 15\%$	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  $\pm 0,83$  mmol/L for glucose values less than 5,55 mmol/L, and within  $\pm 15\%$  for glucose values greater than or equal to 5,55 mmol/L.

## User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 216 lay persons showed the following results: 100% within  $\pm 0,83$  mmol/L of the medical laboratory values at glucose concentrations below 5,55 mmol/L and 98,8% 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

## Customer Service Checklist

When speaking with the Customer Service representative:



1. Have your CONTOUR PLUS blood glucose meter, CONTOUR PLUS test strips, and CONTOUR PLUS control solution available when you call.
2. Locate the model number (A), serial number (B), and UDI code (C) on the back of the meter.
3. Locate the test strips' expiration date on the bottle or foil packet.
4. Check the battery status.

Unique device identifier (UDI) information:



- (01) device ID
- (11) date of manufacture (YYMMDD)
- (10) lot number
- (21) SKU-serial number

**UDI**

## Meter Kit Contents

- CONTOUR PLUS blood glucose meter  
(with two 3-volt CR2032 or DL2032 coin batteries)
- CONTOUR PLUS user guide
- CONTOUR PLUS quick reference guide
- Lancing device
- Lancets
- Carrying case
- CONTOUR PLUS blood glucose test strips  
(not included in all kits)

Supplies that may be needed but not included in your kit:

- CONTOUR PLUS control solution
- Disinfectant solution
- Cleaning wipes
- USB cable
- AST cap
- CONTOUR PLUS blood glucose test strips (if not included)

To replace missing parts or reorder supplies, contact Customer Service. See *Contact Information*. Some supplies are sold separately and are not available through Customer Service.

## 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 compatible Ascensia Diabetes Care software (where supported).

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 *Contact Information*.

## References

1. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
2. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12): 1020-1024.
3. Desachy A, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. *Mayo Clinic Proceedings*. 2008;83(4):400-405.
4. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
5. Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. US Department of Health and Human Services; update March 2, 2011. <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
6. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2021. *Diabetes Care*. 2021;44(supplement 1):S15-S33.

7. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2021. *Diabetes Care*. 2021;44 (supplement 1):S73-S84.
8. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.