EN

Contour next

Blood Glucose Monitoring System

Works with free CONTOUR®DIABETES app.

To check meter online registration availability, visit
www.diabetes.ascensia.com/registration

NO CODING

Second-Chance® sampling

Uses only CONTOUR®NEXT blood glucose test strips.

USER GUIDE

CONTACT INFORMATION

Imported and Distributed by:
Ascensia Diabetes Care UK Ltd
Ascensia House
Albert Road
Newbury, Berkshire
RG14 1DL UK
www.diabetes.ascensia.com

Imported and Distributed by:
Ascensia Diabetes Care Ireland Ltd
10 Earlsfort Terrace
Dublin 2
D02 T380
Ireland

Customer Service: 0345 600 6030 – UK, 1 800 920 111 – IE

Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel, Switzerland

EC REP Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano, Italy

ASCENSIA
Diabetes Care

CE
2797

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INTENDED USE

The CONTOUR NEXT 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 NEXT 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 NEXT 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 NEXT meter works ONLY with CONTOUR NEXT test strips and CONTOUR NEXT control solution.
- Health care professionals, see Section *5 Help: Health Care Professionals.*

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.
- If you are experiencing symptoms of high or low blood glucose, 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.
- **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 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 your Target Range settings with your health care professional.
- Do not calibrate a continuous glucose monitoring device from a control result.
- Do not calculate a bolus 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.[4,5]
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.[4] See Section *5 Help: Cleaning and Disinfection.*
- For complete instructions on cleaning and disinfecting your meter, see Section *5 Help: 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.[4,5]

Small Parts

- 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.

CAUTION

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

- 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.
- 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, such as the USB port.

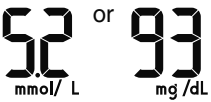
LIMITATIONS

- **Altitude:** This system has not been tested at altitudes higher than 6301 metres.
- **Hematocrit:** CONTOUR NEXT 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 NEXT 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 Next blood glucose meter

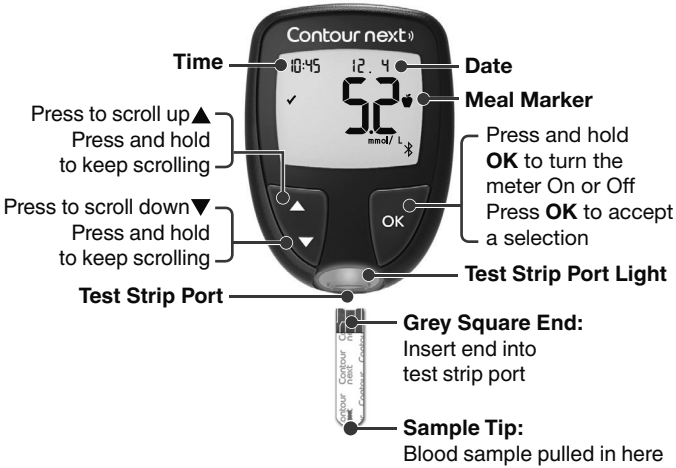
- Your CONTOUR NEXT meter has been preset and locked to display results in mmol/L (millimoles of glucose per litre of blood).
  - Results in mmol/L have a decimal point.
  - Results in mg/dL do not have a decimal point.

  Example: 

  Check your display screen to be sure the results are shown correctly. If not, contact Customer Service. See *Contact Information*.
- The CONTOUR NEXT blood glucose monitoring system has a measuring range of 0.6 mmol/L to 33.3 mmol/L.
  - For results under 0.6 mmol/L or over 33.3 mmol/L:
    - If your meter does not display a value and displays the **LO** screen, **contact your health care professional immediately**.
    - If your meter does not display a value and displays the **HI** screen, wash your hands or the test site and repeat the test with a new strip. If the meter again displays the **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.

1 GETTING STARTED

Your CONTOUR NEXT meter and CONTOUR NEXT test strip



- To exit from the **Logbook** or **Averages** and return to the **Home** screen, press **OK**.
- When a symbol is blinking, you can select it.

Check the Meter Display

Press and hold **OK** 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. Verify that the meter screen fully displays **8.8.8** 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. See *Contact Information*. 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 Section *4 Settings*.

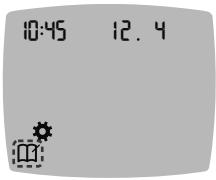
Your Meter Symbols

Symbol	What the Symbol Means
	Yellow Light: test result is **above** Target Range.
	Green Light: test result is **in** Target Range.
	Red Light: test result is **below** Target Range.
▲	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	Test result is above 33.3 mmol/L.
LO	Test result is below 0.6 mmol/L.

Symbol	What the Symbol Means
	Your **Logbook**.
	Meter **Settings**.
	**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: means the **Bluetooth** wireless setting is On; the meter can communicate with a mobile device.
	Low batteries.
	Dead batteries.
	Meter error.
	Reminder feature.
	Sound feature.
	7-, 14-, 30-, and 90-day averages.
	Total number of blood glucose readings used to calculate averages.

The Home Screen

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



- To highlight the **Logbook** or **Settings**, press the ▼ button.
- To enter the **Logbook**, press **OK** while the **Logbook** symbol is blinking.
- To enter **Settings**, press **OK** while the **Settings** symbol is blinking.

Your Meter Features

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.

2 TESTING

Get Ready to Test

Read your CONTOUR NEXT user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing.

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 NEXT meter works only with CONTOUR NEXT test strips and CONTOUR NEXT control solution.

Fingertip Testing

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

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

To perform a quality control check, see Section *5 Help: Control Solution Testing*.

Some supplies are sold separately. See Section *6 Technical Information*: *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.[4] See Section *5 Help: 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 *5 Help: Cleaning and Disinfection.*

High / Low Blood Glucose

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

Refer to your lancing device insert for detailed instructions on preparing the lancing device and fingertip or palm testing.

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.

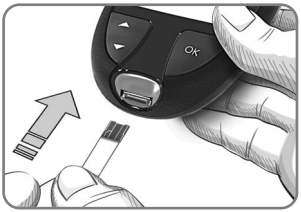
Insert the Test Strip

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

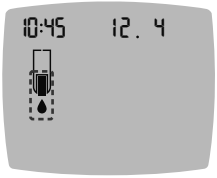
NOTE: If strips are stored in a bottle, tightly close the bottle lid immediately after removing the test strip.

Some supplies are not available in every region.

1. Remove a CONTOUR NEXT test strip.



2. 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.

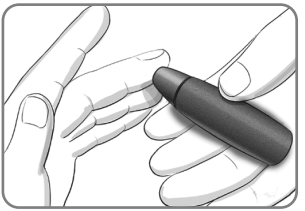
NOTE: After you insert the test strip, apply blood to the test strip within 3 minutes or the meter turns off. Remove the test strip and reinsert it to begin a test.

Get the Blood Drop: Fingertip Testing

NOTE: For 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.

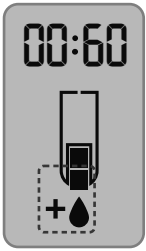
2. Immediately touch the tip of the test strip to the drop of blood.

   The blood is drawn into the test strip through the tip.
3. 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**.

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

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.

About Meal Markers

You can attach a **Meal Marker** to your blood glucose result when the **Meal Marker** feature is turned On.

Your CONTOUR NEXT meter comes with **Meal Markers** turned Off. You can turn **Meal Markers** On and change **Target Ranges** in **Settings** ⚙. See Section *4 Settings*.

NOTE: Not for use on multiple patients.

Symbol	What It Means	Target Range
Fasting	Use when testing after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	The meter compares your result against the **Before Meal Target Range**. (Pre-set to 3.9 mmol/L–7.2 mmol/L)
Before Meal	Use when testing within 1 hour before a meal.	The meter compares your result against the **Before Meal Target Range**. (Pre-set to 3.9 mmol/L–7.2 mmol/L)
After Meal	Use when testing within 2 hours after the first bite of a meal.	The meter compares your result against the **After Meal Target Range**. (Pre-set to 3.9 mmol/L–10.0 mmol/L)
No Mark	Use when testing at times other than after fasting or before or after a meal.	The meter compares your result against the **Overall Target Range**. (Pre-set to 3.9 mmol/L–10.0 mmol/L)

Add a Meal Marker to a Reading

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.**

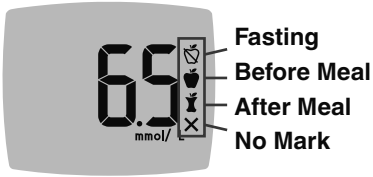
For more information, see Section *2 Testing: About Meal Markers*.

Example:

Do not press OK or remove the test strip yet.

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

To turn **Meal Markers** On, see Section *4 Settings: Set Meal Marker Feature*.



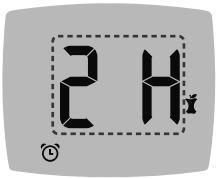
1. If the blinking **Meal Marker** is the one you want, press **OK** *or*
2. To select a different **Meal Marker**, press the ▲ or ▼ button on the meter to scroll between markers.

3. When the **Meal Marker** you want is blinking, press **OK**.
4. If this is a **Before Meal** reading, you can set a **Reminder** to test your blood glucose later. See Section *2 Testing: Set a Test Reminder*.

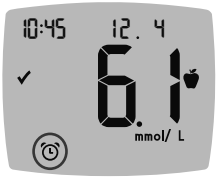
If you do not make a **Meal Marker** selection within 3 minutes, the meter turns off. Your blood glucose reading is stored in the **Logbook** without a **Meal Marker**.

Set a Test Reminder

1. Make sure the **Reminder** feature is On in **Settings**. See Section *4 Settings: Set Reminder Feature*.
2. Mark a blood glucose reading as a **Before Meal** reading, then press **OK**.



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



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

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:

NOTE: To change a **Meal Marker** you selected, you must use the CONTOUR DIABETES app.

NOTE: Not for use on multiple patients.

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

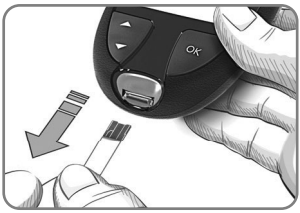
Yellow means **Above Target** ⬆
Green means **In Target** ✓
Red means **Below Target** ⬇

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

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

NOTE: To change an individual target range, see Section *4 Settings: Change Before/After Meal Target Ranges*. To change the Overall Target Range, see Section *4 Settings: Change Overall Target Range*.

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



To turn the meter off, remove the test strip.

Blood glucose test is complete.

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.

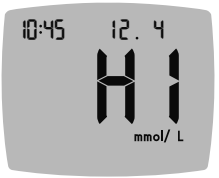
  If you get a similar result, follow your health care professional's advice immediately.

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 5.6 mmol/L in the fasting state and less than 7.8 mmol/L in the postprandial state (after a meal).[6] 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 0.6 mmol/L. **Follow medical advice immediately.** Contact your health care professional.

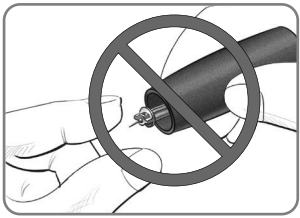


- If the meter beeps once and displays the **HI** screen, your blood glucose reading is over 33.3 mmol/L.
  1. Wash and dry your hands well.
  2. Retest with a new strip.

  If results are still over 33.3 mmol/L, **follow medical advice immediately**.

To turn the meter Off, remove the test strip.

Eject and Dispose of the Used Lancet



1. Do not use your fingers to remove the lancet from the lancing device.
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.**[4,5]
- **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.

Alternative Site Testing (AST): Palm

See the lancing device insert for detailed instructions on Alternative Site Testing.

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.**

Alternative Site Testing is recommended only when it is more than 2 hours after a meal, diabetes medication, or exercise. 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.

For Alternative Site Testing, you must use the clear endcap. Your CONTOUR NEXT meter can be used for fingertip or palm testing. See the lancing device insert for detailed instructions on Alternative Site Testing. To obtain a clear endcap, contact Customer Service. See *Contact Information*.

Do not use AST under the following conditions:

- If you think your blood glucose is low.
- When blood glucose is changing rapidly.
- If you are unable to feel symptoms of low blood glucose.
- If you get AST 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.

3 LOGBOOK

The **Logbook** contains blood glucose test results and their Meal Markers. When the **Logbook** reaches the maximum 800 results, the oldest test result is removed as a new test is completed and saved to the **Logbook**.

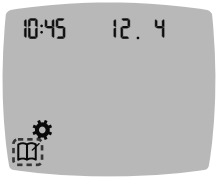
NOTE: Not for use on multiple patients.

Review the Logbook

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

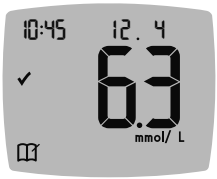
To review entries in the **Logbook**:

1. Press and hold **OK** until the meter turns on, about 3 seconds. The **Logbook** is blinking on the Home screen.



2. To select the blinking **Logbook** symbol, press **OK**.

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 Section *2 Testing: LO or HI Results* for more information.

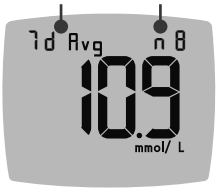
5. To go back to the beginning to review entries, press **OK** to go to the **Home** screen, then select the **Logbook** symbol.

View Averages

1. To enter the **Logbook** from the Home screen, press **OK** while the **Logbook** is blinking.

2. To view your Averages, press the ▲ button from the *first* **Logbook** screen.

7-day Average **Number of tests**



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 **OK**.

4 SETTINGS

In **Settings** you can personalize:

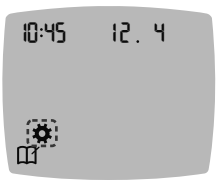
- **Time** format and time.
- **Date** format and date.
- **Sound.**
- **Meal Markers.**
- **Reminder** feature.
- **Target Ranges.**
- **smartLIGHT** feature.
- **Bluetooth** wireless functionality.

NOTE: Press **OK** to accept the current or changed setting before moving to the next setting.

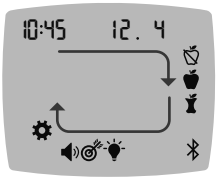
Access Settings

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

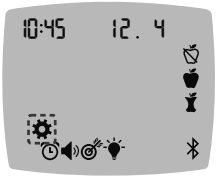
The **Home** screen has 2 options: **Logbook** and **Settings**.



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



4. To scroll through **Settings** options as shown in the image, press the ▲ or ▼ button until the symbol you want is blinking.
5. Press **OK**.

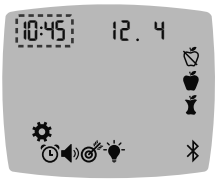


6. To exit from the **Settings** menu and return to the **Home** screen, press the ▲ or ▼ button until the **Settings** ⚙ symbol is blinking.
7. Press **OK**.

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

Change the Time

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

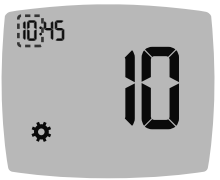


2. When the current time is blinking on the **Settings** screen, press **OK**.
   The time format (12 hour or 24 hour) is blinking.

12 Hour 24 Hour

Time Format

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



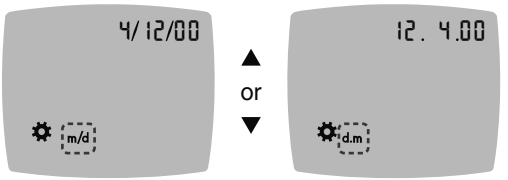
4. To change the hour (blinking), press the ▲ or ▼ button, then press **OK**.

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

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

Change the Date

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button until the current date is blinking, then press **OK**.

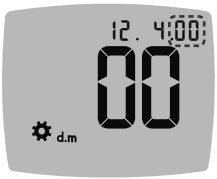


Date Format

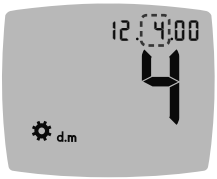
The date format (**m/d** or **d.m**) is blinking.

TURN OVER TO SEE BACK

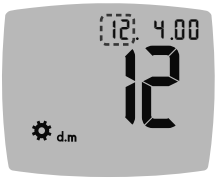
3. To select **Month/Day/Year** (**m/d**) or **Day.Month.Year** (**d.m**), press the ▲ or ▼ button, then press **OK**.



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



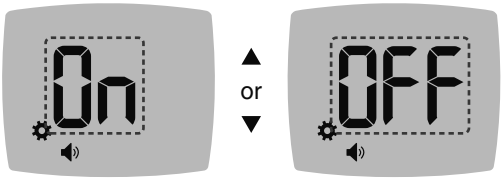
5. To change the month (blinking), press the ▲ or ▼ button, then press **OK**.



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

Set the Sound

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Sound** 🔊 symbol is blinking, then press **OK**.



Sound Symbol: 🔊

3. To turn the **Sound** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

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

When **Sound** is On:

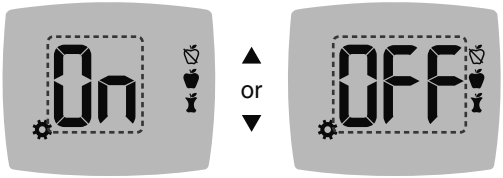
- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

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.

Set Meal Marker Feature

NOTE: Not for use on multiple patients.

1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Meal Marker** symbols are blinking, then press **OK**.



Meal Marker Symbols:

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

3. To turn **Meal Markers** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

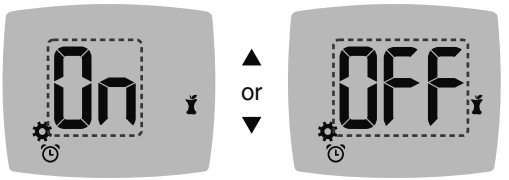
NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

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 Section *4 Settings: Set Meal Marker Feature*.

1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Reminder** symbol is blinking, then press **OK**.

   Your meter comes with the **Reminder** feature turned Off.
3. To turn the **Reminder** feature On or Off, press the ▲ or ▼ button.



Reminder Symbol:

4. Press **OK**.

Change Overall Target Range

WARNING

Discuss your Target Range settings with your health care professional.

Your meter provides a pre-set **Overall Target Range**. You can change the **Overall Target Range** in **Settings**.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** 🎯 symbol is blinking, then press **OK**.

3. To change the blinking **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.
4. Press **OK**.

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

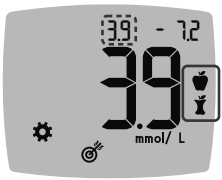
Change Before/After Meal Target Ranges

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

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

1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

Before Meal/After Meal Low Target



The **Before Meal** / **After Meal** **Low** Target number is blinking.

NOTE: There is only 1 **Low** number for both the **Before Meal** and **After Meal** Target Ranges.

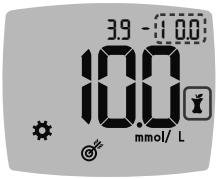
3. To change the blinking **Low** for both Target Ranges, press the ▲ or ▼ button.
4. Press **OK**.

Before Meal High Target

5. To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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

After Meal High Target



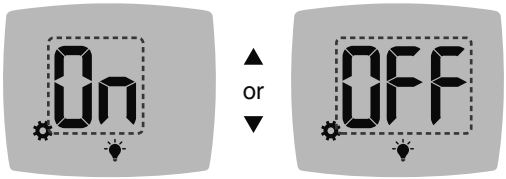
7. To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
8. Press **OK**.

Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a colour that corresponds to your test result.

Yellow means **Above Target** ▲
Green means **In Target** ✓
Red means **Below Target** ▼

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** 💡 symbol is blinking, then press **OK**.



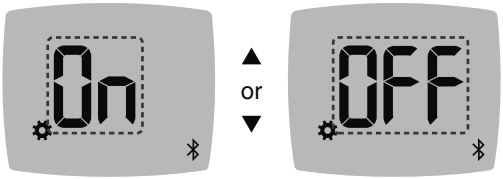
smartLIGHT Symbol: 💡

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

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see Section *4 Settings: Pairing Mode*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** ᛒ symbol is blinking, then press **OK**.



Bluetooth Symbol: ᛒ

3. To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button.
4. Press **OK**.

The CONTOUR DIABETES app for Your CONTOUR NEXT meter

Your CONTOUR NEXT meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet.

You can do the following with your CONTOUR DIABETES app:

- Add Notes after testing that help to explain your results.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Share reports.
- Change meter settings, as necessary.

The CONTOUR DIABETES app:

- Automatically stores 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.
- Syncs your most recent Target Range from the app or meter, across the system.
- Syncs the app date and time to your meter.

Download the CONTOUR DIABETES app

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

NOTE: The CONTOUR NEXT 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.

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.

NOTE: Not for use on multiple patients.

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

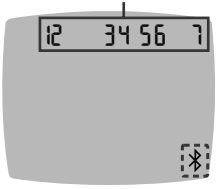
To put your meter in pairing mode:

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

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

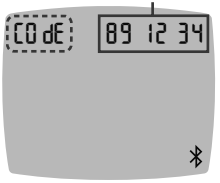
3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.

Meter serial number



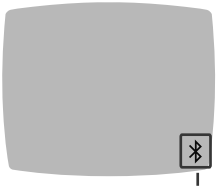
Example: Your meter in pairing mode.

Pass code



When a connection is made, the meter displays the 6-digit pass code.

4. Enter the pass code on the smart device.



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

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

Bluetooth

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.

5 HELP

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, such as the USB port.

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.

Self-Testing

Your CONTOUR NEXT 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.

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 NEXT meter has been tested for 10,950 disinfection cycles using 1 part bleach mixed with 9 parts water.

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** for assistance:

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

NOTE: For health care professionals: The print on the meter buttons may fade after numerous cleaning and disinfection cycles. This will not affect the results of your CONTOUR NEXT system.

Transfer Results to a Personal Computer

You can transfer test results from the CONTOUR NEXT meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need 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.

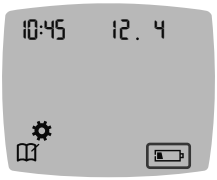
NOTE: Not for use on multiple patients.

USB Port

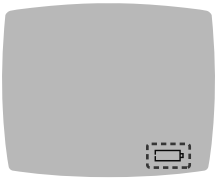
Ensure your meter's USB port door is completely closed when not in use.

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

Batteries

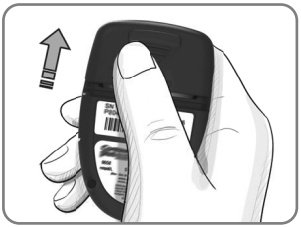


When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.



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

Replace the Batteries



1. Turn off your meter.
2. Turn the meter over and slide the battery cover in the direction of the arrow.

3. 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.

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

6. Slide the battery cover back into place.
7. Discard old 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.

Control Solution

NOTE: Shake the control solution well before testing.

CAUTION: Use only CONTOUR NEXT control solution (Normal, Low, and High) with your CONTOUR NEXT blood glucose monitoring system. Using anything other than CONTOUR NEXT 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 expiry dates on your test materials.

Refer to your control solution insert.

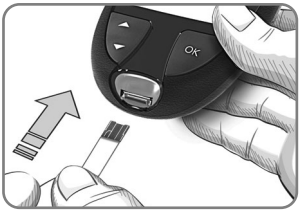
Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your CONTOUR NEXT meter with control solution only when the temperature is 15°C–35°C. Store control solutions between 9°C and 30°C.

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

Control Solution Testing

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

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



2. 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.

3. Shake the control solution bottle well, about 15 times before every use.

   Unmixed control solution may cause inaccurate results.

4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
5. 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.

6. Immediately touch the tip of the test strip to the drop of control solution.
7. **Hold the tip in the drop until the meter beeps.**

   The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the CONTOUR DIABETES app.
8. Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.
9. Remove the test strip and dispose as medical waste or as advised by your health care professional.

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

6 TECHNICAL INFORMATION

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 **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See *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 NEXT 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 *Contact Information*.

Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your CONTOUR NEXT blood glucose meter, CONTOUR NEXT test strips, and CONTOUR NEXT 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' expiry date on the bottle or foil packet.
4. Check the battery status.

Unique device identifier (UDI) information:

UDI

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

Meter Kit Contents

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

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

- CONTOUR NEXT control solution
- Disinfectant solution
- Cleaning wipes
- USB cable
- AST cap
- CONTOUR NEXT 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.

Technical Information: Accuracy

The CONTOUR NEXT blood glucose monitoring system was tested with capillary blood samples from 100 subjects. Two replicates were tested with each of 3 lots of CONTOUR NEXT test strips for a total of 600 readings. Results were compared to the YSI glucose analyzer, which is traceable to the CDC hexokinase method. The following accuracy results were obtained.

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

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	160 of 192 (83.3%)	190 of 192 (99.0%)	192 of 192 (100%)

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

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	262 of 408 (64.2%)	397 of 408 (97.3%)	408 of 408 (100%)

Table 3: System accuracy results for glucose concentrations from 1.9 mmol/L to 29.1 mmol/L

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

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either ± 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L or within ± 15% at glucose concentrations ≥ 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 324 lay persons showed the following results:

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L and 98.60% within ± 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.

Technical Information: Precision

A measurement repeatability study was conducted with the CONTOUR NEXT blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 mmol/L to 19.3 mmol/L. With each blood specimen, each of 3 lots of CONTOUR NEXT test strips was tested 10 times on each of 10 meters for a total of 300 readings. The following precision results were obtained.

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

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
2.23	0.06	0.058–0.068	2.8
4.36	0.07	0.067–0.079	1.7
7.63	0.11	0.102–0.121	1.5
11.80	0.18	0.170–0.202	1.6
18.94	0.24	0.223–0.264	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 NEXT test strips was tested once on each of 10 meters on 10 separate days for a total of 300 readings. The following precision results were obtained.

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

Control Level	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
Low	2.34	0.03	0.032–0.038	1.5
Normal	6.99	0.10	0.096–0.113	1.5
High	20.53	0.38	0.352–0.417	1.9

Specifications

Sample Type: Capillary, venous and arterial whole blood

Hematocrit: 0%–70%

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 0.6 mmol/L–33.3 mmol/L of glucose in blood

Countdown Time: 5 seconds

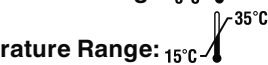
Memory: Stores most recent 800 test results

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: 

Meter Operating Temperature Range: 

Control Testing Temperature Range: 

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)

Second-Chance sampling Conditions: Temperature Range 15°C–35°C, Hematocrit 20%–55%

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

Weight: 53 grams

Meter Life: 5 years (up to 18,250 blood glucose tests)

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 NEXT 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 NEXT meter. The CONTOUR NEXT meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. The CONTOUR NEXT meter meets the requirements of IEC 61326-1 for radio frequency interference.

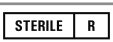
See WARNING in *Important Safety Information* for additional information regarding electrostatic discharge safety.

Hereby, Ascensia Diabetes Care declares that the radio equipment type CONTOUR NEXT 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 NEXT 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)
	Caution
	Do not reuse
	Biological risk
	Sterilized using irradiation
	Batch code
	Control discard date
	Temperature limitations
	Keep dry
	Consult instructions for use
	In vitro diagnostic medical device
	Manufacturer
	Authorized representative in the European Community/European Union
	Catalogue number

Symbol	What It Means
CONTROL L	Control Range Low
CONTROL N	Control Range Normal
CONTROL H	Control Range High
15x	Shake 15 times
UDI	Unique device identifier (UDI)
Σ	Number of test strips included
	Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area. The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment. Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.
	Recyclable material. Separate waste collection. Check your local municipal guidelines. 2 HDPE — High-density polyethylene 4 LDPE — Low-density polyethylene 7 OTHER — Other plastics 21 PAP — Non-corrugated fiberboard (paperboard) 22 PAP — Paper

Principles of the Procedure: The CONTOUR NEXT blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the 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 NEXT 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.
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 June 8, 2017. 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. 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 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Ascensia Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR NEXT test strips and CONTOUR NEXT control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

4. Ascensia Diabetes Care has no knowledge of the performance of the CONTOUR NEXT blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore does not warrant the performance of the CONTOUR NEXT meter when used with any test strips other than CONTOUR NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.
5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any control solution other than CONTOUR NEXT control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any software other than 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 *Contact Information*.