

Contour[®]

Blood Glucose Monitoring System **TS**



USER GUIDE

ARTWORK ROUTING FOR APPROVAL

SCHAWKI!

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INTENDED USE: The CONTOUR®TS system (meter, test strips, controls) is intended for self-testing by people with diabetes and by health care professionals to monitor glucose concentrations in fresh capillary whole blood drawn from the fingertip. In clinical settings, the CONTOUR TS system may also be used with fresh venous and arterial whole blood. The test provides a quantitative measurement of glucose in blood from 0.6 mmol/L to 33.3 mmol/L.

The CONTOUR TS blood glucose monitoring system is not intended for diagnosis of or screening for diabetes mellitus, and is not for use in neonatal care.

Information For Safety

-  Read your CONTOUR TS user guide, the lancing device insert and all instructional materials provided in your meter kit before testing. Please follow all instructions for use and care exactly as described to help avoid inaccurate results.
- Wash and dry your hands well before testing.
- Used test strips and lancets are possible biohazards and must be disposed of as medical waste or as advised by your health care professional.
- The lancing device provided with your kit is intended for self testing by a single patient. It must not be used by more than one person due to the risk of infection.



Warning: Potential Biohazard

Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases. The user should follow the recommendations for prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens.¹

For complete cleaning instructions, see page 13.

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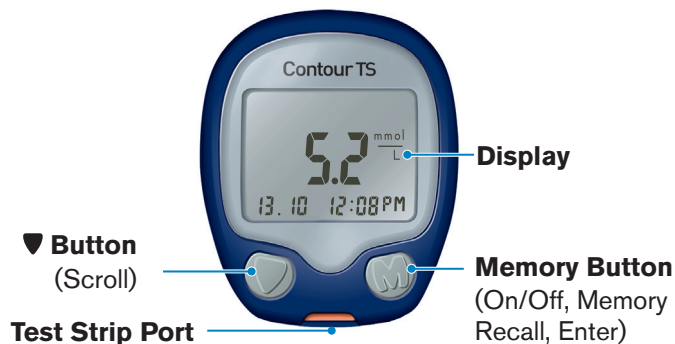
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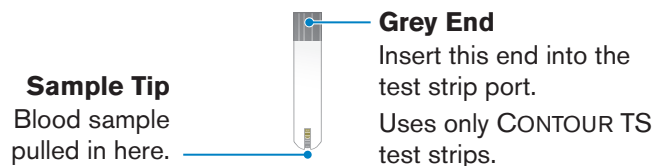
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Your CONTOUR[®]TS Meter



Your CONTOUR[®]TS Test Strip



Your Meter Display

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

While all characters are displayed, it is very important to verify that 8.8.8 is fully displayed. If there are missing segments, see Error Codes and Symbols (pages 24 – 27). This may affect the way you see your results.



Indicates the meter is ready to test.



Indicates it is too cold or too hot for your meter to test accurately.



When battery symbol remains on display screen during testing, the battery is low and needs to be changed.

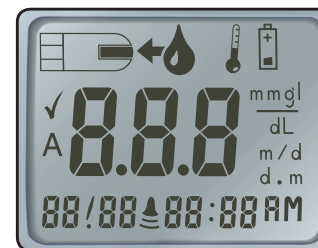
8.8.8

Center area on the display that shows either your test result or any error codes.

✓
Control result marker.

A
14 day average.

🔔
Beeper on/off indicator.



$\frac{\text{mmol}}{\text{dL}}$

Results are displayed as either mmol/L or mg/dL.

$\frac{\text{m}}{\text{d}}$ or $\frac{\text{d}}{\text{m}}$
Displays the date format.

88/88 88:88

Bottom area on the display showing date and time.

AM or **PM** will appear if the meter is in 12 hour setup.

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

Your Meter Features

Easy: The CONTOUR TS blood glucose monitoring system is about simplicity. You will notice its simple approach the first time you see it.

Automatic: Your CONTOUR TS meter is designed with No Coding technology, to automatically code itself every time you insert a test strip. It will even tell you when a test strip is underfilled.



Programmed: Your CONTOUR TS meter has been preset at the factory with the standard date and time for your convenience.

- Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). In some countries, the meters are preset to display units in mg/dL (milligrams of glucose per deciliter);
- Results in mmol/L will always have a decimal point;
- Results in mg/dL will never have a decimal point.

Example: 5.3 $\frac{\text{mmol}}{\text{L}}$ or 96 $\frac{\text{mg}}{\text{dL}}$

Check your display to ensure that results are being displayed in mmol/L. If they are not, contact Customer Service. See the back cover for contact information.

CONTOUR®TS meter CONTOUR®TS test strips

Information For Safety

- Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.** The bottle is designed to keep the test strips dry. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips. This could lead to inaccurate test results.
- Wash and dry your hands well before testing.**
- ⊗ Test strips are for single use only. Do not use a test strip that appears damaged or has been used.**
- 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.
- Do not press the test strip against your finger when testing.** This may block the sample tip.
- Let the meter and test strips adjust to the temperature where you are testing.** Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of a new location before performing a blood glucose test. The meter has been designed to give accurate results at temperatures between 5°C and 45°C.
- Check the expiry dates on your test strips and control solution.** It is important to not use the test strips or control solution if the expiry date printed on the bottle label and carton has passed. For the control solution do not use if it has been six months since you first opened the bottle. It will help to write the six month discard date on the control solution label.



Information For Safety

- **Have all the materials you will need ready before you begin testing.** This includes your CONTOUR®TS meter, the CONTOUR®TS test strips, the lancing device and lancets. You will also need CONTOUR®TS control solution to run a quality control check. CONTOUR TS control solutions are sold separately.
- **⚠ The lancing device provided with your kit is intended for self testing by a single patient. It must not be used on more than one person due to the risk of infection.**
- **⊗ Use a new lancet each time you test because it is no longer sterile after use.**
- Do not perform a blood glucose test when the CONTOUR TS meter is connected to an external device, e.g., computer.
- Use only approved equipment from the manufacturer or certified body such as UL or TUV.
- Examine product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. Contact Customer Service for replacement parts. See the back cover for contact information.



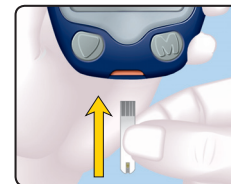
- **All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning. See page 13.**
- **Always wash your hands well with soap and water and dry them before and after testing, handling the meter, lancing device or test strips.**


CONTOUR®TS meter CONTOUR®TS test strips

The following steps are shown in the proper order for performing a blood glucose test, pages 8 – 12.

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a CONTOUR®TS test strip from the bottle.
3. Hold the test strip with the grey end facing up.
4. Insert the grey end into the test strip port on the meter.



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

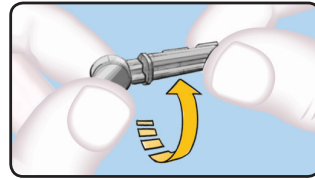
Preparing the Lancing Device

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

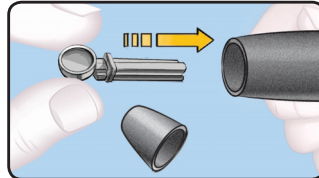


- **The lancing device provided with your kit is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.**
- **Dispose of the used lancet as medical waste or as advised by your health care professional.**
- **⊗ Do not reuse lancets. Use a new lancet each time you test.**

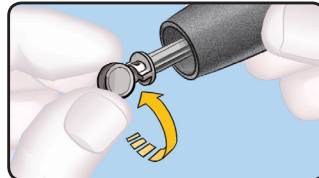
1. Remove the endcap from the lancing device.



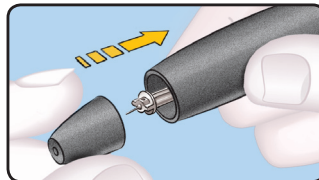
2. Loosen the round protective cap on a lancet by rotating it 1/4 turn, but do not remove it.



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

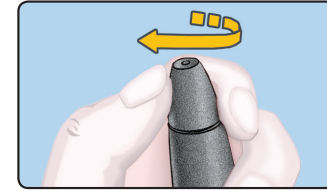


4. Twist off the round protective lancet cap. Save it for disposing of the used lancet.



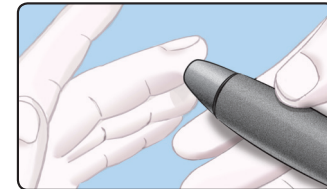
5. Replace the endcap.

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

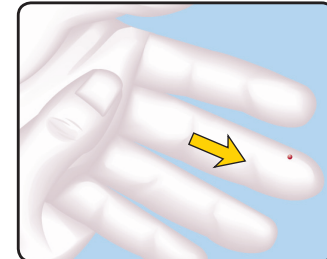


Getting the Blood Drop and Testing

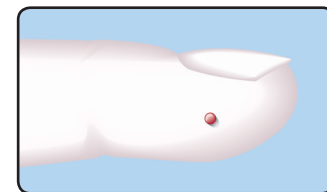
1. Press the lancing device firmly against the puncture site and press the release button.



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



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

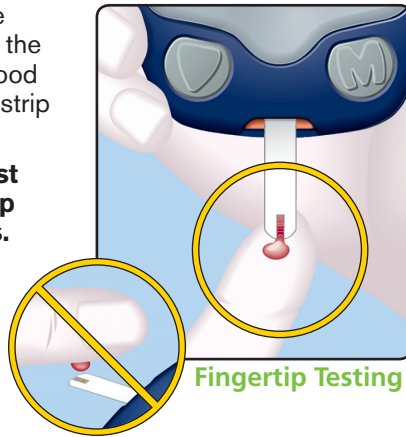


Suggested drop size

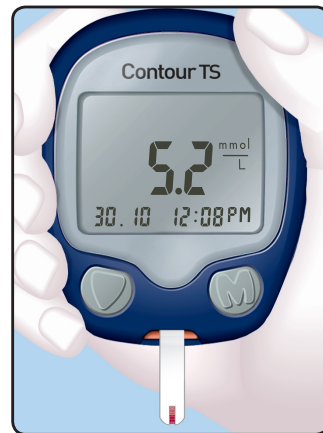
4. Immediately touch the **tip** of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.

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

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

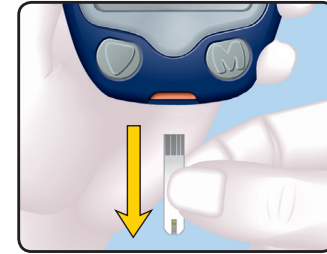


5. After a beep, you will see the meter count down 5 seconds and your blood test result is displayed and automatically stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.



CONTOUR®TS meter CONTOUR®TS test strips

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.



Test Results Expected Values

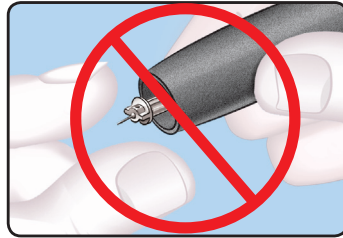
Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Non-diabetic plasma glucose concentrations are normally maintained within a relatively narrow range, roughly 3.9 – 6.1 mmol/L in a fasting state.² **You should consult with your health care professional for expected values specific to your needs.**



- **If your blood glucose reading is under 2.8 mmol/L, or you see LO (less than 0.6 mmol/L) on the meter display, follow medical advice immediately.**
- **If your test result is above 13.9 mmol/L, or you see HI (greater than 33.3 mmol/L) on the meter display, call your health care professional as soon as possible.**
- **Always consult your health care professional before changing your medication based on CONTOUR®TS test results.**


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.



CONTOUR®TS meter CONTOUR®TS test strips



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

Cleaning Your Meter

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



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

Control Solution Testing

Use only CONTOUR®TS control solutions (Normal, Low or High) with your CONTOUR®TS blood glucose monitoring system.

Using anything other than CONTOUR TS control solution could present incorrect results.

You should perform a control test:

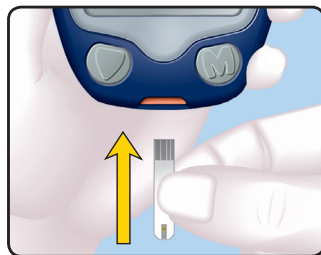
- When using your meter for the first time
- When you open a new bottle or package of test strips
- If you think your meter may not be working properly
- If you have repeated unexpected blood glucose results

Normal, Low or High control solutions are available and sold separately. Always use CONTOUR TS control solutions. Other brands could present incorrect results. If you need help locating CONTOUR TS control solutions, contact Customer Service. See the back cover for contact information.

1. Wash and dry your hands well before testing.
2. Remove a test strip from the bottle and firmly snap the lid closed.

NOTE: Check the expiry date on the test strip bottle and the expiry and discard dates on control solution. Do not use expired materials.

3. Hold the test strip with the grey end facing up.
4. Insert the grey end into the test strip port on the meter.



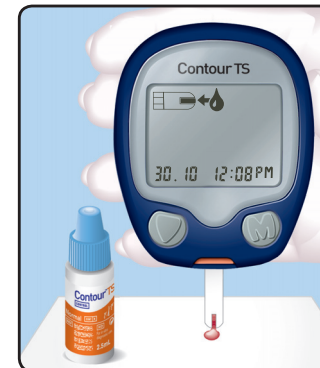
CONTOUR®TS meter CONTOUR®TS test strips

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



5. Gently rock the control bottle before opening to ensure it is mixed well.

6. Squeeze a small drop of control solution on a clean, nonabsorbent surface, such as a piece of wax paper. **Do not apply control solution to your fingertip or to the test strip directly from the bottle.**



7. Immediately touch the **tip** of the test strip to the drop of control solution. The solution is pulled into the test strip through the tip.
8. Hold it in the drop until the meter beeps.

You will see the meter count down 5 seconds until the test is complete and your control test result is displayed.



The meter will automatically recognize and ✓ mark the control result for you.



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.

- Compare your control test result to the ranges provided on the test strip bottle or carton.

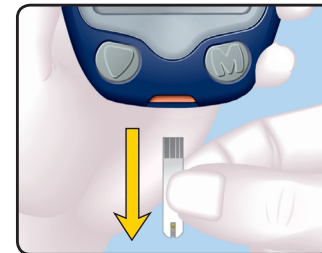


CONTOUR®TS meter CONTOUR®TS test strips

If your control test result is out of range, do not use your meter for blood glucose testing until you resolve the issue. See “What You Should Do” on page 27.

To turn your meter off, simply remove the test strip. Dispose of the used test strip as medical waste.

The result will be automatically ✓ marked and stored in the meter memory. Control results will not be included in your 14 day blood glucose average.



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

Setting the Time, Date and Sound

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

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

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

Setting the Time

The number in the **hour** position will be flashing. Press **▼** until you reach the correct hour.

Press **M** to set.



The number in the **minute** position will now flash. Press **▼** until you reach the correct minutes.

Press **M** to set.



Setting the Date

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

Press **M** to set.



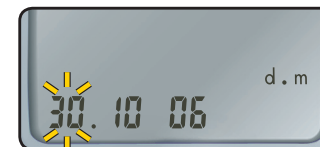
The **month** will now flash. Press **▼** to select the month.

Press **M** to set.



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

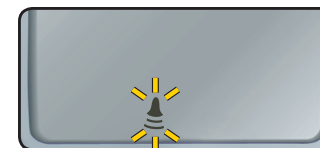
Press **M** to set.



Setting the Sound

The flashing bell symbol will now appear on the display.

This option controls whether you want to hear the beep sound during testing.



Press **M** to set.



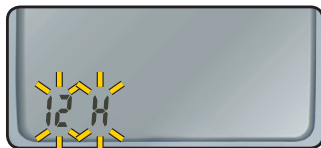
Setting the 12 or 24 Hour Clock

24H will now flash on the display.

Press **▼** to choose the **12H** or **24H** setting.

This option lets you set the meter to display time as a 12 hour setting with AM and PM or as a 24 hour display.

Press **M** to set.



Setting the Month and Day Format

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

Press **M** to set.



When you reach the end of the setup, your meter screen will display all of the current settings and turn off automatically.

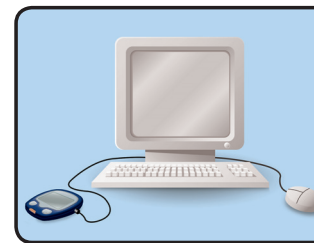


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Transferring Results to a Computer

You can transfer test results from the CONTOUR®TS meter to a computer, where they can be summarized in a report with graphs and tables. To make use of this feature, you need GLUCOFACTS™DELUXE diabetes management software and a USB data cable. The cable is not commercially available but can be requested from Customer Service. See the back cover for contact information.

For a free download of the software go to www.glucofacts.ascensia.com or contact Customer Service. See the back cover for contact information. May not be available in all countries.

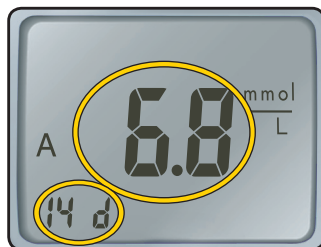


IMPORTANT: The CONTOUR TS meter has not been tested by Ascensia Diabetes Care for use with any software other than diabetes management software from Ascensia Diabetes Care. Ascensia Diabetes Care is not responsible for any erroneous results from the use of other software.

Viewing Stored Test Results

With the meter off, press and release **M** to view stored test results.

The **14 day average** will appear in the center of the display. Any control results are not included in this 14 day average.



Press **M** 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 **▼** to scroll through the results.



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

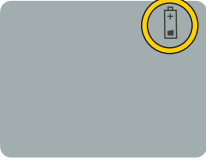
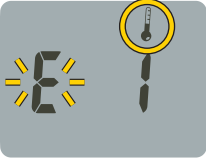
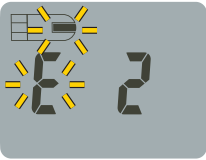
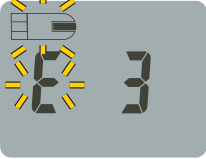
Press **M** to turn the meter off, or it will turn off automatically after three minutes.






NOTES



- Averages include the specified time period plus the current day.
- The meter will hold 250 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.

Error Codes and Symbols:

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	Low Battery – when battery symbol remains on display screen during testing.	Replace the battery as soon as possible (see page 28).
	Temperature out-of-range.	Move to an area that is within the operating range for the meter: 5°C–45°C. Let the meter and test strips adjust to this temperature for twenty minutes before testing.
	The test strip has not filled enough to give an accurate result. <ul style="list-style-type: none"> You may have applied blood more than once on the same strip. Blocked sample tip. Blood drop too small. 	Remove the test strip and repeat the test using a new test strip. <ul style="list-style-type: none"> Do not attempt to apply blood more than once per strip. Do not push strip into skin while filling strip. See suggested drop size on page 9.
	The meter is sensing a used test strip.	Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop in the display before adding the blood sample.

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	Test strip not inserted correctly.	Remove the test strip and insert it properly (see page 7). Use only CONTOUR®TS test strips.
E5 E6 E8 E9	E10 E12 E13	Potential software or hardware issue. Remove the test strip and retest using a new test strip. If you continue to have problems, contact Customer Service. See the back cover for contact information.
	Wrong test strip.	Remove the test strip and retest using only a CONTOUR TS test strip.
	<ul style="list-style-type: none"> Strip disturbed during countdown. Strip degraded due to long exposure out of bottle. Used test strip inserted. 	Remove the test strip and retest using a new test strip. Carefully follow testing instructions in your user guide. If you continue to have problems, contact Customer Service. See the back cover for contact information.


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

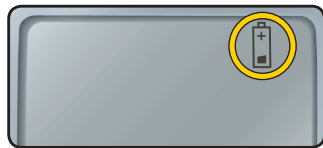
WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	Test result is above 33.3 mmol/L.	<ul style="list-style-type: none"> Wash your hands and the test site. Repeat the test using a new test strip. If your result is still "HI," contact your physician or health care professional immediately.
<p>⚠ CAUTION: Glucose levels above 13.9 mmol/L may indicate a potentially serious medical condition.</p>		
	Test result is below 0.6 mmol/L.	<ul style="list-style-type: none"> Repeat the test using a new test strip. If your result is still "LO," contact your physician or health care professional immediately.
<p>⚠ CAUTION: Glucose levels below 2.8 mmol/L may indicate a potentially serious medical condition.</p>		
The display goes blank after the meter is turned on.	<ul style="list-style-type: none"> Meter will turn off after 3 minutes of inactivity. This feature prolongs your battery life. The battery may need to be replaced. 	<ul style="list-style-type: none"> Try turning the meter on again by pressing M. If display goes blank before 3 minutes, replace battery. <p>See page 28.</p>
Results are not displayed in expected units of measure (mmol/L).	This may affect the way you see your results.	Contact Customer Service. See the back cover for contact information.

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

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
Some display segments do not appear when the meter initially turns on.	Possible meter electronics failure.	Press and hold ♥ while the meter is off. Compare meter display with the picture on page 3. If the display is still not correct, call Customer Service. See the back cover for contact information.
Control test result is out-of-range (too high or too low).	<ul style="list-style-type: none"> Test strip is deteriorated due to exposure to humidity or heat. Control solution is past expiration date or is past the open use date. Test strip is past expiration date or is past the open use date. Incorrect control solution was used. Control solution is not at room temperature. Control solution is not mixed well. 	<ul style="list-style-type: none"> Run another control test with a new test strip. Check all expiry dates. Do not use expired testing materials. Make sure you are using CONTOUR®TS control solution. Wait 20 minutes until control solution is at room temperature. Try again. Gently rock the control bottle to ensure the control solution is mixed well. If result is still out-of-range, retest with a new test strip and control solution. If result is still out-of-range, call Customer Service. See the back cover for contact information.

Changing the Battery

The battery should be replaced when the meter continually displays  or does not turn on. Your CONTOUR®TS meter uses one 3-volt lithium battery (DL2032 or CR2032).



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



NOTE: After replacing the battery you will need to reset the time (see page 18). The date and other formatting choices do not need to be reset. Test results stored in the memory are not erased when the battery is changed.

3. Remove the old battery by placing your finger under the top of the battery and pulling upward. Grasp the battery and remove.
4. Place new battery into the battery compartment with the “+” side up.



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



CAUTION

Keep battery cover and battery out of reach of children. Accidental swallowing could cause suffocation. Lithium batteries are poisonous. If swallowed, immediately contact your doctor or poison control center. Discard batteries according to your local environmental regulations.

Caring for Your Meter

- Store meter in the carrying case provided whenever possible.
- **Wash and dry hands well before handling to keep the meter and test strips free of water, oils and other contaminants.**
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.
- Clean your meter as recommended on page 13.

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, some of the most common symptoms are:³

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



Information For Safety

If you are experiencing any of these symptoms, test your blood glucose. If your test result is under 2.8 mmol/L or above 13.9 mmol/L, contact your health care professional immediately.

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

System Specifications

Test Sample: Venous, arterial or capillary whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 0.6 – 33.3 mmol/L

Results: 5-second countdown

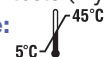
Memory Feature: Stores most recent 250 test results

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

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

Operating Temperature Range:

Humidity: 10% – 93% RH



Dimensions: 71 mm (H) x 60 mm (W) x 19 mm (T)

Weight: 56.7 grams

Sound: A beep sounds whenever a test strip is inserted into the meter, when the test strip is filled with blood or control solution, or when a test result appears on the display screen. Two beeps will sound for an error. To turn off the sound, see Setting the Sound on page 19.













Electromagnetic Compatibility (EMC): The CONTOUR®TS meter complies with the electromagnetic requirement specified in ISO 15197:2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR TS meter. The CONTOUR TS meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The CONTOUR TS meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR®TS meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.




Principles of the Procedure: The CONTOUR®TS blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagent 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 potassium ferricyanide. 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®TS system is designed for use with venous and capillary whole blood. Comparison to a laboratory method must be done simultaneously with aliquots of the same sample. Note: Glucose concentrations drop rapidly due to glycolysis (approximately 5% – 7% per hour).⁴

Symbols Used

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

	Use by date (last day of month)
	Batch code
	Temperature limitations
	Consult instructions for use
	<i>In Vitro</i> Diagnostic Medical Device
	Manufacturer
	Caution
	Catalogue number
	Control Range Normal
	Control Range Low
	Control Range High
	Control Discard Date

	Do not reuse
	Sterilized using irradiation
	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.

Technical Information

Accuracy

The CONTOUR®TS blood glucose monitoring system was tested in 100 capillary blood samples using 600 CONTOUR®TS test strips. Two replicates were tested with each of 3 lots of CONTOUR TS 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 TS meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	77 of 180 (42.8%)	145 of 180 (80.6%)	170 of 180 (94.4%)

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

Difference range in values between YSI laboratory reference method and CONTOUR TS meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	297 of 420 (70.7%)	399 of 420 (95.0%)	416 of 420 (99.0%)

Table 3 – System accuracy results for glucose concentrations between 2.0 and 24.6 mmol/L

Within ±0.83 mmol/L or ±15%	586 of 600 (97.7%)
-----------------------------	--------------------

Acceptance criteria in ISO 15197: 2013 are 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 132 lay persons showed the following results: 100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 95.6% within ±15% of the medical laboratory glucose concentrations at or above 5.55 mmol/L.

Precision

A repeatability study was conducted with the CONTOUR®TS blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 to 18.3 mmol/L. Multiple replicates (n=300) were tested using multiple CONTOUR TS blood glucose meters and 3 lots of CONTOUR®TS blood glucose test strips. The following precision results were obtained.

Technical Information

Precision

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

Mean, mmol/L	Pooled Standard Deviation mmol/L	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
2.20	0.08	0.073 – 0.086	3.6
4.22	0.10	0.094 – 0.112	2.4
7.31	0.16	0.143 – 0.170	2.1
11.06	0.19	0.172 – 0.204	1.7
18.14	0.27	0.248 – 0.294	1.5

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

Control Level	Mean, mmol/L	Standard Deviation, mmol/L	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
Low	2.21	0.03	0.031 – 0.037	1.5
Normal	6.79	0.09	0.083 – 0.098	1.3
High	19.87	0.25	0.230 – 0.273	1.3

Service Information

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

Important

- ▶ Speak to a Customer Service Representative before returning your meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.
- ▶ Have your CONTOUR®TS blood glucose meter and CONTOUR®TS test strips available when you phone. It would also be helpful to have a bottle of CONTOUR®TS control solution nearby.

Check List

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

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

2. Locate the CONTOUR TS test strips' expiry date on the bottle.

3. Check the battery icon on the display. (See page 28, Changing the Battery.)



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®TS test strips and CONTOUR®TS 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®TS blood glucose meter when used with any test strips other than CONTOUR TS test strips, and therefore does not warrant

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the performance of the CONTOUR®TS meter when used with any test strips other than CONTOUR®TS test strips or when the CONTOUR TS test strip is altered or modified in any manner.

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

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY. IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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

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

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Supplies

You can contact Customer Service for supplies. See the back cover for contact information.

REPLACEMENT PARTS

Item

One 3-volt lithium battery DL2032 or CR2032

CONTOUR TS user guide

CONTOUR®TS test strips

CONTOUR®TS control solution, Normal

CONTOUR®TS control solution, Low

CONTOUR®TS control solution, High

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Diabetes Care

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