



TrueSense™

Blood Glucose Monitoring System

User's Manual

For *In Vitro* Diagnostic Use



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Thank you for choosing the MediSense® TrueSense™ Blood Glucose Monitoring System, a product manufactured and supported by Abbott Laboratories, MediSense Products and its authorised distributors. As you already know, regular blood glucose (sugar) testing is often the key to managing your diabetes. The results you gather can help you determine the effects of:

- Food,
- Exercise,
- Diabetes medications.

Regular testing is important because blood glucose levels change throughout the day as you eat, exercise, and take diabetes medications. They can also vary widely during periods of stress or illness.

We at Abbott Laboratories, MediSense Products realise how important it is for you to monitor your blood glucose on a regular basis. To assist you, we have designed the

2· Introduction

Abbott Laboratories/MediSense Products is committed to providing you with support when you are unable to solve or identify a problem with your MediSense TrueSense Sensor. Contact Customer Service at 1800-801-478.

TrueSense system to be dependable, easy-to-use, compact, lightweight and portable. In this user's manual, we provide you and your diabetes care team with important information and step-by-step directions for using the product.

Please read this manual before you use your TrueSense system.

Intended Use

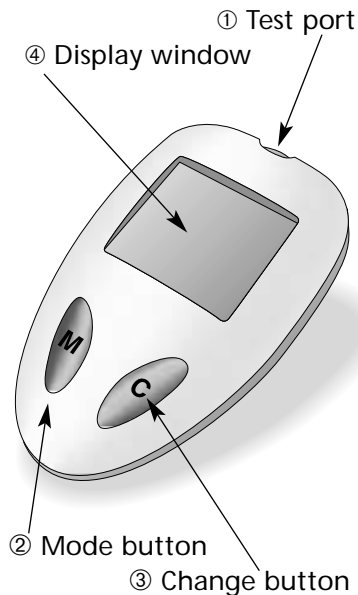
The TrueSense system is intended for use outside the body (*in vitro* diagnostic use). The system is for use with fresh whole blood (e.g., from the finger) **for self-testing or by healthcare professionals**. Healthcare professionals, please see blood glucose electrode package insert for more information regarding sample types.

The System and How It Works

When a blood sample is applied to the electrode, the glucose in the blood reacts with the chemicals on the blood glucose electrode. This reaction produces a small electrical current that is measured and the results are displayed on your sensor.

4 · About your System

TrueSense Sensor



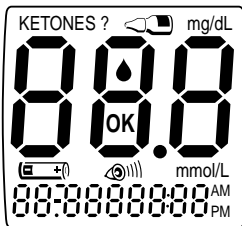
Your TrueSense system is made up of:

- The Sensor,
- The MediSense TrueSense Blood Glucose Electrodes and Calibrator.

Your system measures and displays your blood glucose test results.

- ① **Test Port** is the place you insert your electrodes and calibrators.
- ② **Mode Button (M)** turns your sensor off and on, and saves the options you choose when setting your sensor options.
- ③ **Change Button (C)** allows you to change sensor options and scroll backwards through data.
- ④ **Display Window** shows your:
 - Blood glucose test results,
 - Glucose calibration codes,
 - Previous test results and error messages.

Start up screen



Notes

- If your sensor does not turn on, make sure that you have installed the battery correctly. If the time and date digits on the sensor are displayed as dashes —, —:—, —, you need to reset the time and date; refer to page 6.
- Change toggles between two options or increments.
- Pressing and releasing **Mode** saves set-up changes and moves to the next feature.
- Pressing and holding **Mode** saves set-up changes and turns off the sensor.

Setting your sensor options

You can set the options on your sensor to:

- Switch the beeper off or on.
- Set or change the date and time.
- Select 12 or 24 hour clock display option.
- Select month/day or day/month display option.
- Select mmol/L or mg/dL glucose unit option.

Make sure that your sensor is off and the test port is empty.

- Press and hold the **Mode** button until the Start Up Screen appears.
- Continue to hold the **Mode** button (for about 2 seconds) until the current time and date appear and the beeper icon appears.
- Release the **Mode** button.

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Beeper on



When the flashing beeper icon is displayed, the beeper is turned **off**:

- Press the **C**hange button to turn the beeper on.

When the steady beeper icon is displayed, the beeper is turned **on**:

- Pressing the **C**hange button again switches the beeper off.

When the beeper setting you want is displayed:

- Press the **M**ode button to save your choice.

Time screen



The display now shows the time with the hour digits flashing.

When the hour digits are flashing:

- Press the **C**hange button to change the hour. Each press and release of the button adds one hour.

When the correct hour is displayed:

- Press the **M**ode button to save your choice.

Note: The item that is circled will be flashing on your screen.

Time screen



The display now shows the minute digits flashing.

When the minute digits are flashing:

- Press the **C**hange button to change the minute. Each press and release of the button adds one minute.

When the correct minute is displayed:

- Press the **M**ode button to save your choice.

Date screen



The display now shows the year.

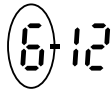
When the year is flashing:

- Press the **C**hange button to change the year. Each press and release of the button adds one year.

When the correct year is displayed:

- Press the **M**ode button to save your choice.

Date screen



The display now shows the date with the month digits flashing.

When the month digits are flashing:

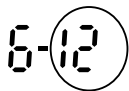
- Press the **C**hange button to change the month. Each press and release of the button adds one month.

When the correct month is displayed:

- Press the **M**ode button to save your choice.

8 · How to Set your Sensor

Date screen



The display now shows the day digits flashing.

When day digits are flashing:

- Press the **C**hange button to change the day. Each press and release of the button adds one day.

When the correct day is displayed:

- Press the **M**ode button to save your choice.

5-14



Time format screen

The display now shows the time format flashing.

The time format can be either 12-hour (AM/PM) or 24-hour:

- Press the **C**hange button to change the time format.

When the time format you want is displayed:

- Press the **M**ode button to save your choice.



8:04 PM

Date format screen

The display now shows the date format flashing.

The date format can either be “mm-dd” (month-day) or “dd.mm” (day-month):

- Press the **C**hange button to change the date format.

When the date format you want is displayed:

- Press the **M**ode button to save your choice.

Glucose Unit
format screen

mmol/L

The display now shows the glucose unit format flashing. The glucose unit format can be either “mmol/L” **or** “mg/dL”:

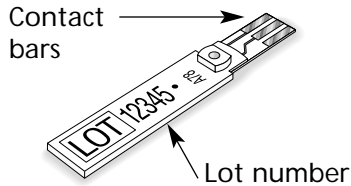
- Press the **C**hange button to change the glucose unit option. Pressing the **C**hange button again switches back to the previous glucose unit option.

When the glucose unit option you want is displayed:

- Press the **M**ode button to save your choice.

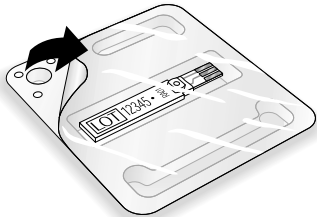
The sensor saves the glucose unit option you have chosen and turns off automatically.

Note: Consult your healthcare professional before changing the glucose unit display on your sensor.



Calibrator

Note: You do NOT need to calibrate your sensor before every test.



When you open a new box of Blood Glucose Electrodes

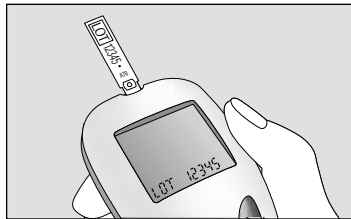
You must code (calibrate) your sensor every time you open a new box of blood glucose electrodes to make sure that your system gives you accurate blood glucose test results.

Each box of blood glucose electrodes includes:

- A Blood Glucose Electrode Package Insert,
- A Glucose Calibrator,
- Foil-wrapped Blood Glucose Electrodes.

How to code (calibrate) your sensor for glucose testing

- Read the blood glucose electrode package insert carefully before you perform your first blood glucose test.
- Remove the calibrator from the new box of blood glucose electrodes.
- Find the three raised bumps on one corner of the plastic container cover and pull the cover back to remove the calibrator, as shown.



OK

LOT 12345

IMPORTANT: Do not discard the calibrator until all of the blood glucose electrodes in the box have been used.

Note: If the LOT number displayed does not match the LOT number on the calibrator, calibrate your sensor again. Make sure you are using the correct calibrator from the box of electrodes you are using. Improper calibration may cause incorrect test results. If the LOT number in the display window still does not match, contact your local Abbott/MediSense office or distributor.

- Use only the calibrator which is in the box of blood glucose electrodes you are using, **or you may get the wrong test results.**
- Hold the calibrator with the LOT number facing up and insert the contact bars into the test port of your sensor, as shown.

The sensor displays the LOT number (for example, LOT 12345) and OK.

- Make sure that the LOT number displayed on your screen matches the LOT number printed on:
 - The Calibrator,
 - The Blood Glucose Electrode Package Insert,
 - The Foil-wrapped Blood Glucose Electrodes.

Your sensor has now been coded (calibrated). Remove the calibrator.

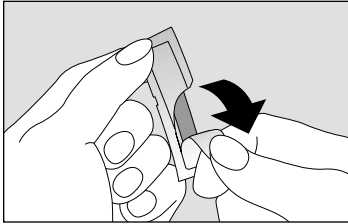
12 · How to Perform Glucose Testing

Notes

- Do not use blood glucose electrodes that have expired. Check the expiration date printed on the box and each foil-wrapped blood glucose electrode. [The month printed refers to the end of that month.](#)
- Use each blood glucose electrode immediately after opening the foil wrapper.
- Do not use wet, bent, scratched, or damaged blood glucose electrodes.
- Do not cut blood glucose electrodes.
- Use each blood glucose electrode only once and then discard.
- If your sensor is moved to a warmer or cooler area (for example, from your pocket or from outside), allow 10 to 12 minutes for it to reach the temperature of the new area.

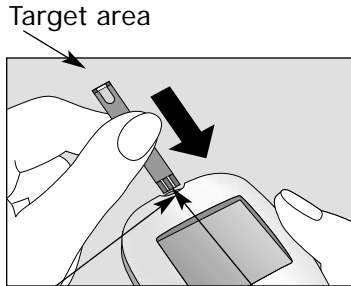
To perform a blood glucose test, you need:

- Your Calibrated TrueSense Sensor,
- A TrueSense Blood Glucose Electrode,
- The Blood Glucose Electrode Package Insert,
- A Lancing Device,
- A New Lancet.
- Before opening a blood glucose electrode and obtaining a blood sample, use warm, soapy water to wash your hands. Warm water helps to increase the blood flow to your fingertips.
- Make sure that your hands are thoroughly dry before handling the blood glucose electrode.



Tear at notch.
Pull down diagonally.

- Open a blood glucose electrode by tearing diagonally at the notch on the side of the foil wrapper, as shown.



Test port Contact bars

- Insert the blood glucose electrode into the sensor test port, as shown. Push the blood glucose electrode in until it stops.

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Start Up Screen

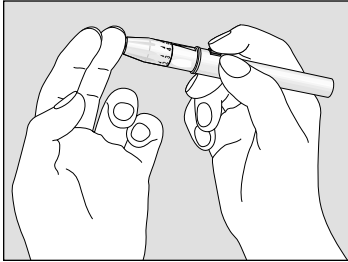


LOT 12345

Note: If the time and date digits on the sensor are displayed as dashes —.—.—.—, you need to reset the time and date; refer to Chapter 2, [How to Set your Sensor](#).

The sensor turns on automatically. The Start Up Screen appears in the display window. If any part of the Start Up screen display is missing, call your local Abbott/MediSense office or distributor. The current time and date appear (if set) followed by the LOT number and the **Apply Blood** icon.

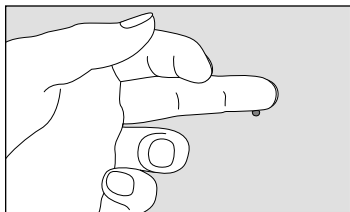
Make sure the LOT number agrees with the LOT number printed on the blood glucose electrode foil.



Lancing device

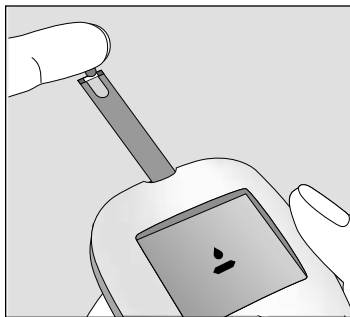
- Obtain a drop of blood using your lancing device and the correct technique; consult your healthcare professional if you need help.
- Do not share a lancing device or used lancet.
- Use a new lancet every time you test.
- Discard the used lancet in a puncture-resistant container.

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Hanging drop of blood

- Obtain a hanging drop of blood similar to the size shown.



Target area

- When the **Apply Blood** icon is displayed, touch the drop of blood to the target area at the tip of the blood glucose electrode. You may use either end-fill or top-fill technique.
- Hold your finger on the target area while the blood is drawn into the target area. The sensor will continue to display the **Apply Blood** icon.
- You may release your finger from the electrode when the test begins. The sensor will beep (if beep-enabled) and display three dashes (- - -) when the test begins.

Note: If the test fails to start, apply a second drop of blood to the target area within 30 seconds of the first drop. If the test fails to start after the second drop of blood is applied, or if more than 30 seconds have passed, discard the blood glucose electrode. Turn off your sensor and repeat the test with a new blood glucose electrode.

Countdown screen



Test result screen

The sensor begins a countdown. Do not remove or disturb the blood glucose electrode during the countdown.

The sensor displays your blood glucose test result. **The sensor will beep (if beep enabled).** It turns off automatically. Pressing the **Mode** button also turns off the sensor.

Your sensor will store your blood glucose test result, and you can record the result in your log book.

Remove the blood glucose electrode and discard properly. You can use the opened foil wrapper to remove and discard your used blood glucose electrode.

KETONES?
17.5
mmol/L
5-14 12:00 PM

Glucose test result

If the screen displays a test result higher than 16.7 mmol/L (300 mg/dL)

If a glucose test result is higher than 16.7 mmol/L (300 mg/dL) with the word ‘**KETONES?**’ flashing, or **Hi** is displayed with the word ‘**KETONES?**’ flashing on the screen:

- Repeat the test with a new blood glucose electrode,
- Check your blood or urine ketone level,
- Follow your healthcare professional’s instructions for ketone testing and for treating a high blood glucose level.

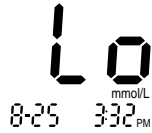
2.8
mmol/L
5-14 12:00 PM

Glucose test result

If the screen displays a test result lower than 2.8 mmol/L (50 mg/dL)

If a glucose test result is lower than 2.8 mmol/L (50 mg/dL), or **Lo** is displayed on the screen:

- Repeat the test with a new blood glucose electrode,
- Follow your healthcare professional’s instructions for treating a low blood glucose level.



Lo
mmol/L
8-25 3:32 PM

If the screen displays **Lo**

Repeat the test with a new electrode when:

- Your sensor displays ‘Lo’,
- Your blood glucose result is unusually low,
- You question your result.



KETONES ?
Hi
mmol/L
8-25 3:32 PM

If the screen displays **Hi**

Repeat the test with a new electrode when:

- Your sensor displays ‘Hi’,
- Your blood glucose result is unusually high,
- You question your result.

Note: ‘Lo’ and ‘Hi’ test results may have a serious medical outcome. Consult your healthcare professional before making any changes to your diabetes medication program.

Notes

The results obtained from performing a glucose control test do **not** reflect your personal blood glucose level.

- Do not use control solutions that have expired. Check the expiration date printed on the box and the control solution bottles.
- When you open the control solution bottles for the first time, write the date on each bottle label. Control solutions can only be used for 90 days after opening.
- See Chapter 3, [How to Perform Glucose Testing](#) for directions on how to use your blood glucose electrodes.
- For control solution ranges, refer to your blood glucose electrode package insert.

Glucose Control Testing

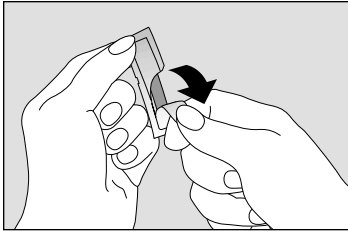
Use only MediSense® Control Solutions to test the performance of your TrueSense sensor and blood glucose electrodes.

Control solution testing should be performed:

- When you open a new box of blood glucose electrodes,
- Before you adjust your diabetes medication,
- When you question your blood glucose test result.

To perform a glucose control test, you need:

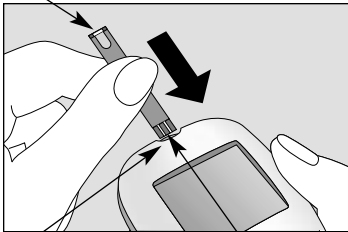
- Your TrueSense Sensor,
- A TrueSense Blood Glucose Electrode,
- The Blood Glucose Electrode Package Insert,
- Control Solutions,
- Control Solutions Package Insert.



Open the electrode foil, as shown.

Tear at notch.
Pull down diagonally.

Target area



Insert the blood glucose electrode into the sensor test port, as shown. Push the blood glucose electrode in until it stops.

Test port

Contact bars



Control test result

Note: Compare the glucose control result to the “Expected Results for Use with MediSense® Control Solutions” printed on the blood glucose electrode package insert. If the glucose control result is not within the expected range, repeat the test with a new blood glucose electrode following the instructions completely. If the result is not within the expected range again, contact your local Abbott/MediSense office or distributor.

When the LOT number and the **Apply Blood** icon are displayed:

- Press the **Change** button once. The icon for the control solution bottle will appear at the top of the display window.
- Turn the control solution bottle over 3 or 4 times to mix the solution. Hold the bottle with the cap down and tap the nozzle once or twice to remove any bubbles in the nozzle.
- Remove cap and apply a drop of control solution to the white target area at the tip of the blood glucose electrode. The test starts automatically when the control solution is detected.
- The sensor displays your glucose control test result and turns off automatically. Pressing the **Mode** button also turns off the sensor.
- Your sensor will store your control test result with the icon for the glucose control bottle, and you can record the result in your log book as a control test.
- Remove the blood glucose electrode and discard properly. You can use the opened foil wrapper to remove and discard your used blood glucose electrode.

Your sensor stores up to 150 glucose and control test results. If you set the date and time option on your sensor **before** performing your blood glucose tests, the review of test results will include the date and time on the display.

Make sure that your sensor is off and the test port is empty.

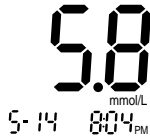
- Press the **M**ode button to turn on your sensor.

The Start Up Screen appears in the display window and is followed immediately by the current time and date and your most recent test result.

- Press and release the **C**hange button once to view the previous test result.

- Each press and release of the **C**hange button displays your test results, from the newest to the oldest test result stored.

- The display shows three dashes (- - -) after your last test result is displayed.



5.8
mmol/L
5-14 8:04 PM

Display results



- - -

- To stop viewing your test results, press the **Mode** button to turn off your sensor.

OK Transferring your test results to a computer

Communication test display

You can transfer the test results stored in your sensor to a computer. If you would like additional information about this feature and how to obtain software, please contact your local Abbott/MediSense office or distributor.



Low battery icon

Note: Do not remove the old battery until you have a new battery to install. Make sure to reset the time and date once you install a new battery.

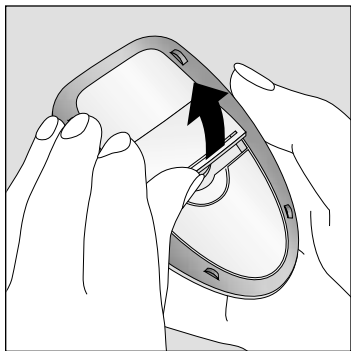
When the power level of the battery is getting low, your sensor will alert you by displaying the low battery icon.

You may still use your sensor and the results will be accurate. However, it is recommended that you replace the battery at this time.

If the power level of the battery is too low, the screen displays the battery icon and the sensor turns off automatically.

Use a CR 2032 coin cell battery only.

Your sensor comes installed with one CR 2032 coin cell battery. To save your battery power, the sensor turns off automatically after a glucose test. Pressing the **Mode** button also turns off the sensor.



Note: If your sensor does not turn on, make sure that you have installed the battery correctly. If the time and date digits on the sensor are displayed as dashes —.—.—.—, you need to reset the date and time; refer to Chapter 2, [How to Set your Sensor](#).

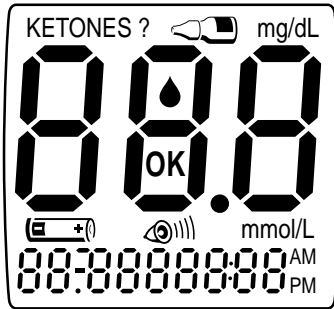
How to replace your battery

- Lift the battery door as shown.
- Remove the old battery and insert a new CR 2032 coin cell battery with the plus sign (+) facing up and towards the battery door.
- Hook the battery door onto the sensor and push on the door until you hear a click.
- Make sure the battery is inserted correctly by turning on your sensor.
- Be sure to discard the old battery in compliance with local government regulations.

Caring for your sensor

Your sensor does not require special cleaning. If the surface of your sensor becomes dirty, you can clean it by using a damp cloth and mild soap or detergent.

When not in use, store your sensor in the wallet. Do not try to clean the test port, and do not place or immerse your sensor in water or other solvent.



Start Up Screen

Note: If your sensor does not turn on, make sure that you have installed the battery correctly. If the time and date digits on the sensor are displayed as dashes — .—:—:—, you need to reset the time and date; refer to Chapter 2, [How to Set your Sensor](#).

Reviewing System Displays

You can review your calibration code, the date and time setting, and error messages stored in your system.

Make sure that your sensor is off.

- Press the **Change** button to turn on your sensor.

The Start Up Screen appears in the display window. If any part of the Start Up screen display is missing, call your local Abbott/MediSense office or distributor.

- The calibration LOT number is displayed first.
- Pressing the **Change** button displays the date and time setting alternating with the year.
- Continue to press and release the **Change** button to display the last 10 Error Codes stored in your sensor.

Error Codes

The display shows an error code (**E-1 through E-7**), the date and time of that error, and a three-digit qualifier (e.g. 701).

E-1

- Continue to press and release the **Change** button to display the last 10 Error Codes stored in your sensor.
- Sensor temperature is too high or too low to operate properly. The sensor can only operate between 0° and 50°C.

Action:

- Move to warmer or cooler temperature. Wait 10 to 12 minutes for your sensor to reach the temperature of the new area. Repeat test.

E-2

- Sensor error.

Action:

- Remove electrode, turn off sensor and repeat test.
- If error occurs again, call your local Abbott/MediSense office or distributor.

E-3

Test error.

Action:

- Repeat test with a new blood glucose electrode.
- If error occurs again, refer to Chapter 3, *How to Perform Glucose Testing* or call your local Abbott/MediSense office or distributor.

E-4

· Test error.

Action:

- May be caused by glucose being too high to be read by the system. Repeat test with a new blood glucose electrode.
- If error occurs again, call your healthcare professional and follow their instructions.

E-5

· Blood applied too soon.

Action:

- Repeat test with a new blood glucose electrode. Wait until **Apply Blood** icon appears before applying the blood.
- If error occurs again, call your local Abbott/MediSense office or distributor.

E-6

· Error during calibration.

Action:

- Try to calibrate your sensor again. Be sure you are using the calibrator that came in the box of blood glucose electrodes you are using. Refer to Chapter 3, *How to Perform Glucose Testing*.

- If error occurs again, call your local Abbott/MediSense office or distributor.

E - 7

- Blood glucose electrode error.
- Blood glucose electrode is either damaged, inserted incorrectly or not compatible with sensor.

Action:

- Refer to Chapter 3, *How to Perform Glucose Testing*. Repeat test with a new blood glucose electrode.
- If error occurs again, call your local Abbott/MediSense office or distributor.

LOT - - - - -

- Sensor not calibrated for test.

Action:

- Calibration required. You need to code (calibrate) your sensor for glucose testing. Refer to Chapter 3, *How to Perform Glucose Testing*.

- - -

- Three dashes (- - -) are displayed after your last Error Code is displayed.
- To stop viewing the system display screens, press the **Mode** button to turn off your sensor.

Dimensions and Weight

Length	9.9 cm
Width	5.9 cm
Thickness	2.1 cm
Weight	50.0 g

Storage Temperature Range

Sensor	-25° to 55°C
Electrodes	See Blood Glucose Electrode Package Insert.
Control Solution	4° to 30°C

Power Source One CR 2032 lithium coin cell battery

Battery Life Approximately 1500 tests

Assay Range See Blood Glucose Electrode
Package Insert.

Control Solution Range

See Blood Glucose Electrode
Package Insert.

To get correct test results, make sure you test within the system operating range.

System Operating Range

Temperature The system operating range is the operating range of the blood glucose electrode you are using. See Blood Glucose Electrode Package Insert.

Relative Humidity 10% to 90%, non-condensing

Sensor Operating Range

Temperature 0° to 50°C

Relative Humidity 10% to 90%, non-condensing

Distributed by:

Abbott Diagnostic Division
MediSense Products
666 Doncaster Road
Doncaster 3108
Victoria, Australia
ABN 95 000 180 389

MediSense Products
Customer Service
1 800 801 478

8am-6:30pm EST - Monday to Friday

Made in USA or Germany, as marked on the sensor.

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