MediSense®

Optium™

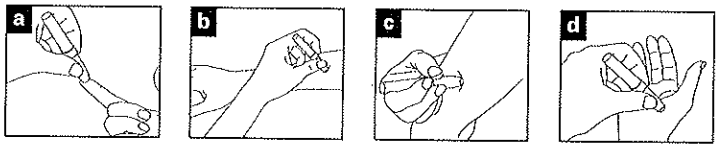
Read This First

IMPORTANT: Read these instructions for use and the User's Guide supplied with your sensor before you monitor your blood glucose. Failure to follow instructions will cause incorrect results.

Blood Glucose Electrodes with TrueMeasure™ Technology

What are my electrodes for?

MediSense® Optium™ Blood Glucose Electrodes are for use with MediSense® Optium™ and Optium™ Xceed™ sensors. The electrodes are designed to quantitatively measure glucose (sugar) in fresh capillary whole blood from a.) the fingertip, b.) the forearm, c.) the upper arm, or d.) the base of the thumb. The electrodes are for use outside the body (*in vitro* diagnostic use) and are for self-testing or healthcare professional use.



What's in my electrode box?

- Electrodes individually wrapped in foil packets
- 1 Calibrator
- 1 Instructions for use
- 1 Information card

What else do I need that is not in my electrode box?

- MediSense Optium or Optium Xceed sensor
- User's Guide
- MediSense® Control Solutions
- Lancing device and disposable lancets

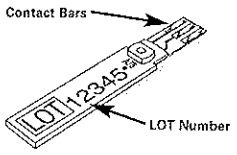
IMPORTANT FIRST STEP: CALIBRATION

Why must I calibrate my sensor?

You must calibrate your sensor so it can recognize the electrode you are using. This ensures that your results are accurate. Failure to calibrate properly will cause incorrect results.

When should I calibrate my sensor?

You must calibrate your sensor each time you open and use a new box of electrodes. Use only the calibrator that comes with the new box of electrodes. When the box is empty, throw the calibrator away.



How do I calibrate my sensor?

1. Hold the calibrator with the LOT number facing toward you. Insert the calibrator into the electrode port. Push it in until it stops.
2. Check that the LOT number matches on **all** of these items: Sensor display window, electrode calibrator, electrode instructions for use, electrode foil packet.

How do I check my system?

Use a MediSense Control Solution to do a control solution test when you question your results and want to confirm that your sensor and electrodes are working properly.

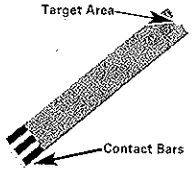
For information on how to obtain Control Solutions, please call Customer Service: Australia 1800 801 478, or New Zealand 0800 106 100. Other countries, contact your local Abbott Laboratories, Abbott Diabetes Care office or distributor.

Control results must be within the "Expected Results for Use with MediSense Control Solutions" printed on these instructions for use.

How do I obtain a blood drop?

- Before you obtain a blood drop, make sure the sample site is clean, dry, and warm. To warm the sample site, wash it in warm water, rub the skin vigorously for a few seconds, or apply a warm pad to it.
- Hang your arm down before lancing your finger or base of the thumb, to help blood flow.
- To obtain a blood drop from the arm, use a fleshy area away from bone. Avoid areas where there is a lot of hair.
- Avoid squeezing the sample site.
- Apply the blood drop to the electrode immediately.

How do I monitor my blood glucose?



1. Remove the electrode from its foil packet. The information card in your box of electrodes shows how to open the foil packet.
2. Insert the contact bars at the end of the electrode into the electrode port of the sensor. Gently push the electrode in until it stops. The sensor turns on automatically.
3. Obtain a blood drop. Follow the instructions for use packaged with the lancing device.
4. Touch the blood drop to the white target area at the end of the electrode. The blood is drawn into the electrode.

What if the countdown does not start? If the countdown does not start, you might not have applied enough blood to the electrode. Apply a second drop of blood to the electrode within 5 seconds of the first drop. If the countdown still does not start or if more than 5 seconds have passed, discard the electrode, turn off your monitor, and repeat steps 1-4.

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

What does my result mean?

The expected glucose range for a non-diabetic, non-pregnant fasting adult is 4.1-5.9 mmol/L (74-106 mg/dL).[1] One to two hours after meals, levels should be less than 8.9 mmol/L (160 mg/dL),[2] according to WHO Guidelines.

Consult your healthcare professional to determine the range that is appropriate for you.

IMPORTANT - What if my result is unusually low or high?

High or low blood glucose results may have serious medical consequences. If your blood glucose result is higher than 16.7 mmol/L (300 mg/dL), lower than 2.8 mmol/L (50 mg/dL), or the result does not reflect how you feel, check that your sensor is calibrated correctly and repeat the test with a new electrode. You may also use a MediSense Control Solution to check the performance of your system.

Follow your healthcare professional's advice before you make any changes to your diabetes medication program.

IMPORTANT - How do I take care of my electrodes?

- Use the electrode immediately after opening its foil packet.
- Your electrodes should be stored at a temperature between 4° – 30°C (39° – 86°F). Storage outside this range may cause incorrect results. Keep away from direct sunlight and heat.
- Use each electrode once and then discard it.
- Do not use out-of-date electrodes. Check the expiration date printed on the electrode box and on every electrode foil packet. If only the year and month are printed on the electrode, then the expiration date is the last day of the month. For example, "EXP 2007/03" means the electrode expires on March 31, 2007.
- Do not use an electrode that is wet, bent, scratched or damaged.
- Do not use the electrode if its foil packet has a puncture or tear in it.

LOT 43662

Expected Results for Use with MediSense Control Solutions

Low:	31 — 61	mg/dL,	1·7 — 3·4	mmol/l
Mid:	68 — 124	mg/dL,	3·8 — 6·9	mmol/l
High:	240 — 389	mg/dL,	13·3 — 21·6	mmol/l

What else do I need to know?

- The MediSense Optium and Optium Xceed systems can read blood glucose levels between 1.1 and 27.8 mmol/L (20 and 500 mg/dL).
- Use MediSense® Optium™ Blood Glucose Electrodes at temperatures between 15° – 40°C (59° – 104°F) and 10% and 90% relative humidity (the amount of moisture in the air) for best results.
- Clinical testing demonstrates that altitudes up to 2,195 metres (7,200 feet) above sea level do not affect results.

IMPORTANT - If you choose to use a sample from the forearm, upper arm, or base of the thumb:

- Consult your healthcare professional before you use any one of these sites to monitor your blood glucose.
- Contact Customer Service for further information: Australia 1800 801 478, or New Zealand 0800 106 100. Other countries, contact your local Abbott Laboratories, Abbott Diabetes Care office or distributor.
- Sampling from any one of these alternative sites may cause minor bruising and may leave marks that go away in a short time.
- There may be times when alternative site results are different from fingertip results. This happens when glucose levels change rapidly (for example, after you eat a meal, take insulin, or during or after exercise).
- Use alternative sites to monitor before, or more than two hours after, you eat a meal, take insulin, or exercise.
- **Do not** use blood samples from alternative sites when:
  1. You think your blood sugar is low,
  2. You have been diagnosed with hypoglycemic unawareness,
  3. The results from alternative sites do not match the way you feel, or
  4. It is within two hours of eating a meal, taking insulin, or exercising.

Are there important messages that I need to know about?

The following messages may mean you have obtained a blood glucose result that requires immediate attention or there may be a problem with the electrode:

- **LO** means your blood glucose may be lower than 1.1 mmol/L (20 mg/dL).
- **HI** means your blood glucose may be higher than 27.8 mmol/L (500 mg/dL).
- **Test Error 2** (MediSense® Optium™ sensors) or **E-3** (Optium™ Xceed™ sensors) means there may be a test error.
- **Test Error 4** (MediSense Optium sensors) or **E-4** (Optium Xceed sensors) means your blood glucose may be too high to be read by the system.

If any of these messages shows, check that your sensor is calibrated correctly and repeat the test with a new electrode. If the same message shows again or the result does not reflect how you feel, contact your healthcare professional **immediately.** You may also use a MediSense® Control Solution to check the performance of your system. Follow your healthcare professional's advice before you make any changes to your diabetes medication program.

IMPORTANT: Please confirm that the correct unit of measure shows on your sensor with every glucose result.

If you have any questions and/or need assistance, please call Customer Service or your local Abbott Laboratories, Abbott Diabetes Care office or distributor.
Australia: 1800 801 478
New Zealand: 0800 106 100

Important Information for Healthcare Professionals

Note: Capillary blood may be collected into heparin-containing or potassium EDTA-containing capillary tubes and used within 30 minutes. Do not use tubes containing fluoride or oxalate.

Limitations of Procedure

- This electrode is not designed for use with arterial, venous, neonatal, serum or plasma samples.
- Haematocrit range is 30%-60%.
- High levels of paracetamol, up to 662 µmol/L (10 mg/dL), will not affect results.
- Test results may be erroneously low if the patient is severely dehydrated, or severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state (with or without ketosis). Similar observations have been reported in the literature for other blood glucose monitoring systems.
- Extremely high levels of the following substances at the following concentrations do not affect results: uric acid, 1.2 mmol/L (20 mg/dL); ascorbic acid, 130.3 µmol/L (2.3 mg/dL); unconjugated bilirubin, 684 µmol/L (40 mg/dL); cholesterol, 13.0 mmol/L (500 mg/dL); and triglycerides, 11.3 mmol/L (1000 mg/dL).
- Do not use during xylose absorption testing.

Test Principle

When the blood sample is applied to the electrode, the glucose in the blood reacts with the chemicals on the electrode, producing a small electrical current. This current is measured and a result is then displayed by the sensor. The size of the current depends on the amount of glucose in the blood sample.

Composition

Glucose Dehydrogenase (*Microbial*)	≥ 0.03U
NAD+ (as sodium salt)	≥ 1.0 µg
Phenanthroline quinone	≥ 0.02 µg
Non-reactive ingredients	≥ 16.3 µg

Performance Characteristics

The performance of MediSense Optium Blood Glucose Electrodes has been evaluated in both laboratory and clinical studies.
Assay Range: 1.1-27.8 mmol/L (20-500 mg/dL) **Test Time:** 5 seconds

Calibration Reference

The MediSense Optium Blood Glucose Electrode is calibrated against the YSI Glucose Analyser (YSI Inc.). The YSI whole blood glucose results are multiplied by 1.12 to provide plasma-equivalent glucose values for the calibration of MediSense Optium Blood Glucose Electrodes.

Precision

Precision testing shows that results typically vary by no more than 3.8% to 5.2%. Please see Table 1.

Accuracy

Capillary blood glucose results obtained by lay users at 3 clinical centers were compared with those obtained using the YSI Analyzer, a laboratory instrument. Please see Table 2.

These studies show that the MediSense® Optium™ and Optium™ Xceed™ systems compare well with the laboratory reference method.

Table 1 - Precision

	Low	Mid-Low	Mid-High	High
Mean mmol/L (mg/dL)	2.4 (43.9)	5.6 (100.3)	8.0 (144.4)	20.0 (361.0)
SD mmol/L (mg/dL)	0.13 (2.3)	0.22 (4.0)	0.30 (5.4)	0.94 (16.9)
CV %	5.2	4.0	3.8	4.7

Table 2 - Accuracy

No. of samples	350
Slope	0.98
Intercept mmol/L (mg/dL)	0.3 (5.8)
r (corr. coef.)	0.97
Glucose range mmol/L (mg/dL)	2.7–27.7 (50–499)

References

1. Burtis, C.A. & Ashwood, E.R., Clinical Chemistry, Third Edition, Philadelphia, W.B. Saunders Co. (1999) p. 1815.
2. Definition, diagnosis and classification of Diabetes Mellitus and complications – 1999 WHO Report (WHO/NCD/NCS/99.2) Page 52 (Table 1 – Values for diagnosis for diabetes).

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