



Sof-Tact™

Blood Glucose Electrodes

If you have any questions and/or need assistance, call MediSense Products Customer Support: 1 800 801 478 (Australia) 0800 106 100 (New Zealand). In the event that you cannot reach Customer Support, contact your healthcare professional. Outside of Australia, please contact your local Abbott Laboratories, MediSense Products office or distributor.

Important: To ensure accurate results, you must read the MediSense® Sof-Tact™ User's Guide before testing.

Intended Use

For self-testing use outside the body (*in vitro* diagnostic use) with the MediSense Sof-Tact Diabetes Management System for quantitatively measuring glucose in fresh capillary whole blood. MediSense Sof-Tact Electrodes are not for use with Precision Q+D®, Precision Xtra™, MediSense® Optium™, MediSense® Card, MediSense® Pen, and ExacTech®.

Storage and Use

- Store the electrodes at temperatures between 4° and 30°C (39° and 86°F). Keep away from direct sunlight and heat.
- Do not use the electrodes beyond the expiration date printed on the foil packet and outer box.
- Insert the electrode into the monitor immediately after opening the foil packet.
- Do not use wet, bent, scratched or damaged electrodes.
- Use the electrode only once and then discard.

Precautions

- Always calibrate (code) the MediSense Sof-Tact Monitor with each new box of electrodes.
- Use only the calibrator supplied with the electrodes. Keep the calibrator until all the electrodes in the box have been used.
- Use only MediSense Sof-Tact electrodes with the MediSense Sof-Tact Monitor.

Important: There may be times when results from alternate sites may differ from fingertip results.

Sample Collection and Preparation

Testing on Port 1: The recommended sites to use are:

- The top surface of the forearm,
- The outside of the upper arm,
- The base of the thumb. This site is only recommended when you have trouble testing on the other test sites. If you have difficulty testing at this site, hanging your arm down before lancing may help increase blood flow.

Before obtaining a blood sample, wash the site with warm soapy water. Warm water helps increase blood flow. Make sure your skin is completely dry after washing the site. Port 1 of the Sof-Tact Monitor lances your skin and obtains the sample for you, applying it directly to the electrode.

Testing on Port 2: (For use when obtaining a sample from the fingertips.)

Before obtaining a blood sample, use warm soapy water to wash your hands and dry completely. Warm water helps to increase the blood flow to your fingertips. If you have difficulty in obtaining a blood sample, hanging your arm down before lancing your finger may also help increase the blood flow. Avoid excessive squeezing of the puncture site. When the capillary blood sample is obtained, it must be used immediately on the electrode in Port 2.

Quick Reference Procedure

Please read the MediSense Sof-Tact User's Guide for detailed testing and calibration (coding) procedures.

Materials provided: MediSense Sof-Tact Blood Glucose Electrodes and calibrator.

Materials required but not provided: MediSense Sof-Tact Monitor and User's Guide, lancing device, lancets, and MediSense® Low and High Control Solutions.

Calibration:

1. Insert the contact bars of the calibrator into the monitor. The monitor turns on automatically.

2. **LOT** and the lot number appear in the display window.
3. Check that this lot number matches the number on the calibrator and electrode packet. Calibration is complete.

Note: You can only use Port 2 to calibrate your monitor.

Blood Glucose Test on Port 1

1. Open the Sof-Tact cover.
2. Insert the contact bars of the electrode into Port 1 of your monitor. The monitor turns on automatically.
3. Loosen the cap from a new lancet and insert it into the lancet holder until it stops. Remove the already loosened lancet cap from the lancet, making sure not to bend the needle.
4. Firmly close the Sof-Tact cover.
5. Rest the monitor **gently** against a cleaned area of skin and press the main button. The monitor will lance the skin, draw a blood sample and apply the blood directly to the electrode. When the sample is detected, the test countdown begins automatically. Your blood glucose result will appear in 20 seconds.

Blood Glucose Test on Port 2

1. Insert the contact bars of the electrode into Port 2 of your monitor. The monitor turns on automatically.
2. When **Apply Blood** appears in the display window, obtain a drop of blood. Touch the drop of blood to the target area. When the sample is detected, the test countdown begins automatically. Your blood glucose result will appear in 20 seconds.

Test Results

- Blood glucose results are displayed as mmol/l or mg/dL, depending on the glucose unit of measurement you have selected. It is important that the correct units are selected. Consult your healthcare professional.
- If **LO** appears in the display window, the monitor has determined that your blood glucose result is lower than 1.7 mmol/l (30 mg/dL) or there may be a problem with the electrode. Repeat the test with a new electrode. If **LO** appears again,

LOT

Expected Results for Use with MediSense® Control Solutions

Low:

Normal-Mid:

High:

follow your healthcare professional's instructions.

- If **HI** appears in the display window, the monitor has determined that your blood glucose result is higher than 25 mmol/l (450 mg/dL). Repeat the test with a new electrode. If **HI** appears again, follow your healthcare professional's instructions.
- If an error message appears on the display, repeat the test with a new electrode. If the same message appears, refer to the User's Guide for an explanation and the appropriate response.
- If **Test Error 4** appears during the testing, this may mean your glucose result is extremely high and beyond the measuring capabilities of your monitor or there may be a problem with the electrode. Repeat the test with a new electrode. If **Test Error 4** appears again, follow your healthcare professional's instructions.
- **High or low results that are incorrect may have serious medical consequences. If your blood glucose result is unusually high [greater than 16.7 mmol/l (300 mg/dL)] or low [lower than 2.8 mmol/l (50 mg/dL)], or if you question your results, repeat the test with a new electrode. In this situation, MediSense Controls can be used to confirm the correct functioning of the system. Consult your healthcare professional before making any changes to your diabetes medication program.**

Expected Results for Non-Diabetic, Non-Pregnant Adults¹

Fasting values: 4.1-5.9 mmol/l (74-106 mg/dL)

Two hours after 75 grams of glucose: Less than 7.8 mmol/l (140 mg/dL)

Limitations of Procedure

- This system is not designed for use with arterial, venous, serum or plasma samples.
- This system is not designed for neonatal use.
- Use between 18° and 30°C (64° and 86°F) and 10% and 90% relative humidity or you may get erroneous results.
- Clinical testing demonstrates that altitudes up to 2,195 meters (7,200 feet) above sea level do not affect results.
- No significant effect was found for haematocrits between 30% and 60%. Haematocrits below 30% may yield higher results and haematocrits higher than 60% may yield lower results.
- High levels of acetaminophen, up to 662 µmol/l (10 mg/dL), will not affect results.

Reference

1. Burtis, C.A. & Ashwood, E.R., *Clinical Chemistry*, Third Edition, Philadelphia, W.B. Saunders Co. (1999) p. 1815.

Made under one or more US patents: 6,071,251; 5,509,410; 5,727,548; 5,682,884; 5,820,551; 6,206,841. Additional US patents pending. Foreign patents pending and issued.

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- 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.
- There may be differences between alternate site and fingertip testing during conditions of rapidly changing glucose. Sof-Tact has been designed for both alternate site and fingertip testing. When you are testing because you think your blood glucose is low (hypoglycemia) or if you lose the ability to know when your blood glucose has fallen low (hypoglycemic unawareness), we recommend using a fingertip sample on Port 2 of your Sof-Tact Monitor.
- 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, 170 µmol/l (3 mg/dL); unconjugated bilirubin, 342 µmol/l (20 mg/dL); cholesterol, 13.0 mmol/l (500 mg/dL); and triglycerides, 33.9 mmol/l (3000 mg/dL).
- Xylose may produce elevated results which may occur only during a xylose absorption test for diagnostic evaluation of malabsorption.
- This system can be pre-loaded with an electrode for use up to 8 hours later when maintained at recommended test conditions.
- Alternate site testing may cause minor bruising and may leave marks that go away in a short time.
- **Healthcare professionals:** This system is not designed for venous or arterial blood. It is designed for capillary blood. Capillary (collected into capillary tubes) blood samples are to be used in Port 2, can be collected into tubes containing lithium heparin or potassium EDTA (do not use tubes containing fluoride or oxalate or sodium citrate) and must be tested within 30 minutes.

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 then a result is displayed by the MediSense Sof-Tact Monitor. The size of the current depends on the amount of glucose in the blood sample.

Composition

The reagent area of each electrode contains:

Glucose dehydrogenase (<i>Microbial</i>)	≥ 0.04 U
NAD ⁺ (as sodium salt)	≥ 7.2 µg
Phenanthroline quinone	≥ 0.4 µg
Non-reactive ingredients	≥ 16.0 µg

Performance Characteristics

Precision

Precision testing shows that results typically vary by no more than 3.5% to 5.0% from the average value. Testing was performed within a laboratory using venous blood samples on the system. Refer to data table (1) at the end of this insert.

Accuracy

Accuracy testing using alternate site and fingerstick samples shows that results compare well with a laboratory reference method and that results are comparable between trained operators and lay users. The accuracy of the system was assessed at five independent sites by comparison with the YSI Glucose Analyzer as used in clinical laboratories and adjusted to approximate plasma values. The data was obtained using fresh capillary whole blood. The glucose range was 2.6-19.3 mmol/l (47-347 mg/dL). Combined data for fingerstick samples (Table 2) and alternate site samples (Table 3) are shown at the end of this insert. Combined data (Table 4) shows that the Sof-Tact arm glucose results at various post-prandial times compare well with finger glucose results obtained with a lab method.

Table 1	Low	Mid-Low	Mid-High	High
Mean, mmol/l (mg/dL)	2.91 (52.4)	4.86 (87.4)	6.91 (124.4)	21.4 (384.6)
SD, mmol/l (mg/dL)	0.14 (2.6)	0.22 (3.9)	0.31 (5.6)	0.73 (13.2)
CV, %	5.0	4.5	4.5	3.5
Table 2				
Fingerstick Sample				
No. of samples	378			
Slope	0.97			
Intercept, mmol/l (mg/dL)	0.27 (4.89)			
r	0.97			
Table 3				
Alternate Site Sample				
No. of samples	354			
Slope	0.98			
Intercept, mmol/l (mg/dL)	0.039 (0.70)			
r	0.96			
Table 4				
Difference between Arm and Finger Glucose Results after a Meal or Sugary Drink				
Time after a Meal or Sugary Drink	0-60 minutes	61-120 minutes	121-180 minutes	
Number of patients	107	100	53	
Mean bias, mmol/l (mg/dL)	-0.46 (-8.3)	-0.01 (-0.2)	-0.039 (-0.7)	
Mean bias, %	-3.8%	0.7%	-0.1%	