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In Touch®

Blood Glucose Test Strips Instructions For Use

livongo™ health

PRINCIPLE AND INTENDED USE

The **In Touch® Blood Glucose Test Strips** (**In Touch® strips**) are used with the **In Touch® Blood Glucose Meter** (**In Touch® meter**) in the quantitative measurement of glucose in fresh capillary blood from the fingertip. The **In Touch® meter** is intended for use by people with diabetes at home as an aid to monitor the effectiveness of the diabetes control program and should not be used for the diagnosis of/or screening for diabetes mellitus. **In Touch® Blood Glucose Test Strips** are thin strips. The strips have a chemical reagent system. They work with the **Livongo Health In Touch® Blood Glucose Meters** to measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the meter. The amount of glucose is then calculated based on this current. The result is shown on the meter display. The meters are calibrated to display plasma equivalent results. The system is used to monitor how well the diabetes control programs work. **In Touch® Test Strips** can be used only outside the body. They are used by persons with diabetes for self-testing purposes. **In Touch® Blood Glucose Monitoring System** is for single patient use only. Do not share with others. For *in vitro* diagnostic use.

COMPOSITION

Each test strip has reactive and non-reactive chemicals. These chemicals are: Glucose Oxidase (from *Aspergillus Niger*) <25 IU, Mediator <300 , Buffer, and Non-reactive Ingredient. Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Store test strips in their protective vial. Store with their cap on tight. This keeps them working properly.
- Store in a cool, dry place between 41-86 °F (5-30 °C) and 10-90% relative humidity and keep out of direct sunlight.
- Use the test strips at room temperature. This provides precise results.
- Keep the text side up and blank side down when you insert the strip contact bars into the strip port.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners with bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap as soon as you remove a test strip.
- Use the test strip as soon as it is removed from the vial.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Do not use your test strips past the unopened vial expiration date. The date is printed on the vial. Otherwise, you may get incorrect test results.

Note: All expiration dates are printed in Year/Month format. 2015/01 means January 2015.

- A new vial of test strips may be used for 6 months after first opening. After 6 months they will expire. Write the opened expiration date on the vial label after opening.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Your Blood Glucose Meter is for single patient use. Do not share it with others including family members. Remember to follow the required pre-cleaning and disinfection procedure. Please refer to the "Caring for Your **In Touch® Blood Glucose Monitoring System**" in your User's Manual. This procedure is important to prevent the potential transmitting of infectious diseases.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give an incorrect result.
- Do not use test strips that are torn, bent, or damaged.
- Do not reuse test strips.
- Apply sample only to the tip of the test strip. Do not apply to the top of the test strip. This may result in a false reading.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This can cause false readings.
- Keep the test strip vial away from children and animals.
- Consult your doctor before making any changes to your treatment plan.

MATERIALS PROVIDED

- Test Strips • Package Insert

Please contact Customer Support at **1-800-945-4355** for information about purchasing test strips.

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter • Sterile Lancets • Lancing Device • Control Solution

Please contact Customer Support at **1-800-945-4355** to obtain a control solution kit.

INSTRUCTIONS FOR USE

See your Owner's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial. Remove a test strip. Replace the cap immediately. This protects the test strips from moisture in the air.
2. Run the test following the instructions in your Owner's Manual.
3. The test result will be shown on the meter display. This result should fall within the target range. Your doctor should recommend your target range. If your results are higher or lower, ask your doctor what to do. Always consult your doctor before changing your treatment plan.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a doctor. Together you can set your own range of expected blood glucose values. You can also arrange your testing times. In addition, you should discuss the meaning of your blood glucose results together. Expected blood glucose levels for people without diabetes:[1]

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Be careful with your blood glucose meter. See the Owner's Manual for how to take good care of your meter. Do a quality control test to make sure that the meter and test strips are working well together. Follow the control test procedure in your User's Manual. Two ranges CTRL 1 and CTRL 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. Contact Customer Support for information on purchasing control solution.

You should confirm your control solution results. Make sure the Control Solution 1 tests fall within the CTRL 1 range. Make sure the Control Solution 2 tests fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood. The system may not be working properly. If you cannot correct the problem, contact Customer Support for help.

LIMITATIONS

- The **In Touch® meter**, test strips and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The **In Touch® meter** should not be used to test critically ill patients and In Touch® meter should not be used to test neonates.
- The **In Touch® Test Strips** test fresh capillary whole blood from the fingertip. Do not use with serum or plasma samples.
- The **In Touch® Blood Glucose Monitoring System** is for self-testing by users to test fresh capillary blood from the fingertip.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 20-600 mg/dL.
- Fatty substances have no major effect on test results. These include triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL.
- Acetaminophen, uric acid, and ascorbic acid (vitamin C) (when occurring in blood at normal or high therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results.
- The **In Touch® Blood Glucose Monitoring Systems** have been tested to work properly up to 8,516 ft (2,595 meters).
- Blood samples from patients in shock, severe dehydration or a hyperosmolar state (with or without ketosis) have not been tested. It's not recommended to test those samples with **In Touch® Blood Glucose Monitoring Systems**.
- Dispose of blood samples and materials with care. Treat all blood samples as if they are infectious materials. Follow all local regulations.
- All parts of the kit are considered biohazardous and potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

PERFORMANCE CHARACTERISTICS

The precision and accuracy of the **In Touch® meter** is calibrated by using an YSI (Model 2300 STAT PLUS) Glucose Analyzer as the reference instrument. It is traceable to the NIST reference standard.

Reproducibility, Precision

Ten replicate assays were each run on ten **In Touch® Blood Glucose Meters**. Heparinized venous blood samples at five concentration levels were used in the testing. The results of all three lots combined provided the following estimates.

MEAN Blood glucose, mg/dL	Standard Deviation mg/dL (SD)	% Coefficient of Variation (CV)
47.33	1.77	3.73
75.7	2.37	3.2
129.37	4.31	3.3
207.67	7.14	3.43
326.63	11.33	3.43

Intermediate Precision

Ten replicate assays from three strip lots were run on ten **In Touch® Blood Glucose Meters**. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results of the results combined from the three strip lots provided the following estimates.

#	MEAN	Standard Deviation mg/dL or Coefficient of Variation (CV)
All Three Lots Combined	37.5 mg/dL	1.45 mg/dL
	119.0 mg/dL	2.8%
	350.0 mg/dL	2.3 %

System Accuracy

System accuracy studies were conducted independently using lay users. Each individual subject obtained their own fingertip sample and self-tested their blood glucose with the **In Touch® Blood Glucose Meter** on the three lots of test strips. Blood was taken from 102 users. The fingertip samples from the same subjects were then analyzed on an YSI Model 2300 STAT PLUS Glucose Analyzer that served as the reference standard to determine the system accuracy of the **In Touch® Blood Glucose Meter** in the hands of lay persons. The results presented below are the results from the first replicates obtained by lay persons using the **In Touch® Blood Glucose Meter** and **In Touch® Blood Glucose Test Strips.**

Linear Regression Results: In Touch® (y) vs. YSI Reference (x) Lay User					
Sample Site	Slope	Intercept	R	R^2	N
Fingertip	0.9987	0.4456	0.9941	0.9882	102

The sample range was 48.2 to 391.5 mg/dL for **In Touch® Blood Glucose Meter** testing with blood sampled from fingertip sites.

Lay User Fingertip Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
68/93 (73.1%)	87/93 (93.5%)	92/93 (98.9%)	93/93 (100.0%)

Lay User Fingertip Site: System Accuracy Results for Glucose Concentration <75mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/9 (66.7%)	9/9 (100.0%)	9/9 (100.0%)

For complete instructions, please refer to the Owner's Manual included with your meter. For additional questions or issues with this product, please contact Customer Support at **1-800-945-4355**. Customer support is available 24 hours a day, 365 days a year.

REFERENCES

1. Standards of Medical Care in Diabetes – 2014, Diabetes Care - 2014 v 37: S1 January 2014
2. FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
3. "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

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