Table of Contents

Chapter 1. About Your GlucoSure® Plus Blood Glucose Monitoring System

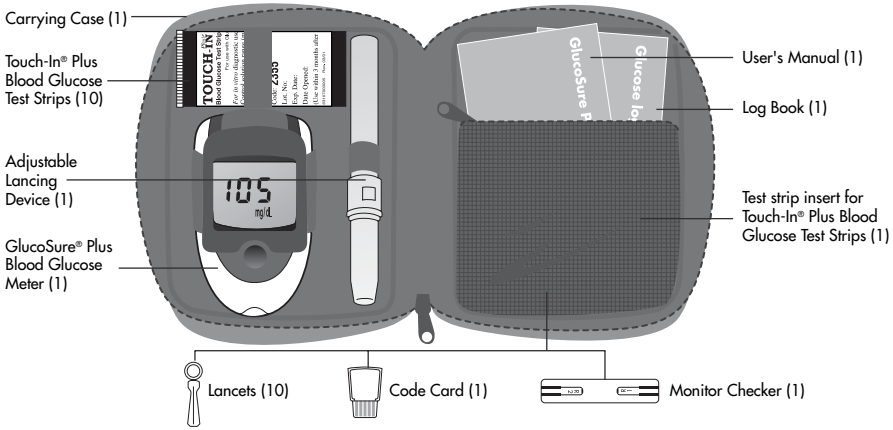
Thank you for choosing the GlucoSure® Plus Blood Glucose Monitoring System to help you manage your blood glucose (blood sugar) levels. All of the information that will be needed to use and maintain the GlucoSure® Plus Blood Glucose Meter is included in this manual. Read it carefully before using the system.

Utilizing Biosensor Technology, your GlucoSure® Plus Blood Glucose Monitoring System provides an easy and precise way of measuring the level of glucose (sugar) in capillary blood from the finger at specific points in time. The results are plasma referenced, which means that the results obtained from the GlucoSure® Plus Blood Glucose Monitoring System is comparable to the results you get in a laboratory.

The GlucoSure® Plus Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) and provides important information relating to blood glucose control. Your GlucoSure® Plus Blood Glucose Monitoring System is designed for both self-testing by an individual and for use by healthcare professionals.

Contents of Kit

The GlucoSure® Plus kit package includes the following items.



* The kit contents may vary in some certain areas.
Contact the dealer if you find difference from the above.

GlucoSure® Plus Blood Glucose Meter

Display Screen

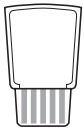
Large, easy-to-read window guides you through testing, displaying results, and error messages using simple words or symbols.

Push Button

- *Recalls test results in the memory. Refer to chapter 5. p.30 "Using Meter Memory" for details [i].*
- *Press and hold to turn off meter.*

Test Strip Holder

Insertion site for test strips and monitor checker. Located at the bottom-front side of the meter. When a test strip or the monitor checker is inserted, the meter will power on automatically. When the test strip or the monitor checker is removed, the meter will power off automatically.



Code Card

The code card programs the meter for a specific lot of test strips. A new code card comes with each new package of test strips.

Monitor Checker

Used to confirm that the GlucoSure® Plus Blood Glucose Meter is functioning properly. Refer to Chapter 2. p.12 "Monitor Checker Test" for details 📖.

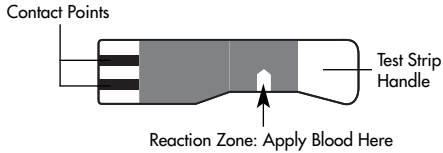
Code Card Port

Insertion site for the code card. Located at the top-back of the meter.

Battery Compartment

Located on the back of the meter. Holds one 3V Lithium coin cell battery (CR2032). Refer to Chapter 7. p.33 "Changing the Battery" 📖.

Touch-In® Plus Blood Glucose Test Strips



Contact Points Sense the position and orientation of the Test Strip.
Test Strip Handle The only area to be touched when handling the Test Strip.
Reaction Zone The area where the blood sample or Control Solution is applied.

The GlucoSure® Plus Blood Glucose Meter is designed specifically to detect glucose in whole blood with the Touch-In® Plus Blood Glucose Test Strip only. The Touch-In® Plus Blood Glucose Test Strips come in a moisture-proof, light-protected bottle. It is important that the bottle is kept well sealed at all times and the cap is replaced immediately after a strip is removed.

Contrex™ Plus Glucose Control Solution (optional)

Standard glucose concentration solution required to perform the "**Quality Control Testing**" in Chapter 2, p.13 to check for system accuracy, practice test procedure, and when using a new lot of Touch-In® Plus Blood Glucose Test Strips.

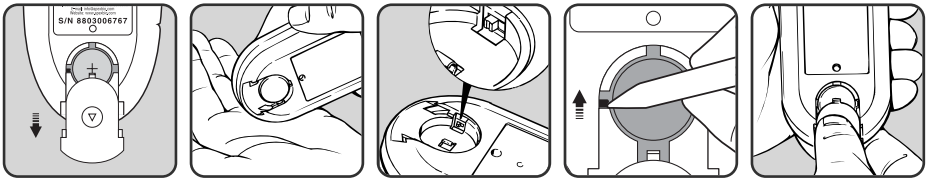
Chapter 2. Before Testing

Changing Unit of Measurement

Your GlucoSure® Plus Blood Glucose Meter can display test results in either mg/dL or mmol/L. The factory setting is mg/dL. Consult your healthcare professional before changing the unit of measurement.

Material you will need:

- Your GlucoSure® Plus Blood Glucose Meter



Step 1: Remove the battery cover at the backside of the Meter.

Step 2: Remove the battery from the battery compartment.
Step 3: Locate a switch on the left side in the battery compartment.
Step 4: Slide the switch downwards for setup of measurement unit at mg/dL, or push the switch upwards for setup at mmol/L.
Step 5: Install the battery, and re-place the battery cover.

Monitor Checker Test

The Monitor Checker Test will help ensure that the electronics in your GlucoSure® Plus Blood Glucose Meter is working properly. This test should be done on a brand new meter or when the performance of the meter needs to be confirmed.

Materials you will need:
- Monitor Checker (included in kit)
- Your GlucoSure® Plus Blood Glucose Meter

Step 1: Insert the Monitor Checker (R1 end) into the test strip holder until you hear a "beep".
Step 2: When the Meter Display Screen shows smiling face " ☺ " it means your meter

is functioning properly and you can proceed to the next step. If the display screen shows a crying face " ☹ " then repeat the testing procedure. If " ☹ " continues to appear, refer to Chapter 8, p.34 "**Message Interpretations & What to do**" 🛈.

Step 3: Repeat the testing procedures steps 1 through 2 on the R2 end of the Monitor Checker.

Quality Control Testing

Perform Quality Control Testing when:

- You first get your meter, before performing a blood glucose test.
- You first begin to use a new bottle of Touch-In® Plus Blood Glucose Test Strips.
- You suspect your GlucoSure® Plus Blood Glucose meter and Test Strips are not working properly.
- The blood glucose results do not reflect how you feel.
- When your Test Strips have been exposed to extreme temperatures (⚠ see Touch-In® Plus Blood Glucose Test Strip Insert for operation ranges).
- Practice the test procedure.

Two levels of Contrex™ Plus Glucose Control Solutions are available for quality control testing. Each level tests a different range of glucose concentration.

⚠**IMPORTANT:**

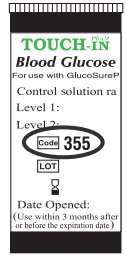
- The acceptable range for the control solution is listed on the package of test strips.
- Use only the Contrex™ Plus Glucose Control Solutions with the Touch-In® Plus Blood Glucose Test Strips. Other brands of glucose solution may produce inaccurate result.
- Always check the expiration date . **DO NOT** use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened; discard any unused control solution three months after opening .
- **DO NOT FREEZE**. Store the control solutions at room temperature 15°C 30°C .
- If the result of the control solution test is outside of the expected range printed on the test strip package, **DO NOT** use the system to test for blood glucose. Repeat the control solution test until the result falls within the expected range. If the result continues to be outside of the expected range, call our authorized dealer for service.
- **DO NOT** touch the test area with the tip of the control solution bottle.
- **DO NOT** apply a second drop of control solution to the test strip.
- Replace the bottle cap on the control solution bottle immediately after use.

Materials you will need:

- Contrex™ Plus Glucose Control Solutions Level 1&2 (optional items, contact our authorized dealer for purchasing information).
- A brand new Touch-In® Plus Blood Glucose Test Strip.
- Your GlucoSure® Plus Blood Glucose Meter.

Step 1: Perform the Monitor Checker Test, refer to Chapter 2, p.12 "**Monitor Checker Test** " 📖.

Step 2: After the display screen of the meter showing " ☺ ", the screen will then display the current code number being used. Verify that code number on screen is the same with the code number printed on the bottle label and remove a test strip from the test strip bottle.



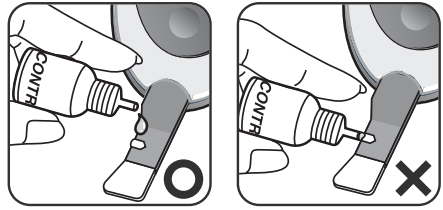
⚠IMPORTANT:

1. Do not use test strip that has expired. Check the expiration date ⌛ that is printed on the test strip bottle and package.

2. Use each test strip immediately after removing it from the bottle.
3. After removing a test strip from the bottle, replace the bottle cap immediately and close it tightly.
4. Do not use wet, bent, or scratched test strips.
5. Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place ☼.
6. Record the "date opened" on the test strip bottle label when you first open it. Discard the bottle and any remaining test strips after 3 months .

Step 3: Insert a brand new Touch-In® Plus Blood Glucose Test Strip into the test strip holder of the Meter. The screen will show "ctrl." This will ensure the control results will not be stored into memory.

Step 4: When the screen shows a symbol "💧" , apply a drop of Contrex™ Plus Level 1 Glucose Control Solution (solution with green bottle cap) on top of the yellow reaction zone of the test strip. Do not apply



the control solution at the edge of the yellow reaction zone.

Step 5: The display screen will show timing bars"-----". The bars will flash and gradually diminish for countdown.

Step 6: After the timing bars disappear, the screen will show test result. Compare the reading on the screen to the Level 1 range printed on the test strip package. The test result falling within the range means the meter and the test strip are working together properly. Remove the test strip.

Step 7: To perform test of Level 2 control solution (solution with blue bottle cap), repeat steps 1-6.

⚠IMPORTANT:

If the test result is not within the expected range, repeat the control solution testing. If the results continue falling outside the expected range, call our authorized dealer.

Chapter 3. Glucose Testing

Coding the Meter

Before you can begin testing on your GlucoSure® Plus Blood Glucose Meter, you must "code" the meter. Coding the meter ensures accurate test results when you perform a test. A new code card is packaged along with each box of Touch-In® Plus Blood Glucose Test Strips.

Materials your will need:

- A code card for the Touch-In® Plus Blood Glucose Strips
- A Touch-In® Plus Blood GlucoseTest Strip
- Your GlucoSure® Plus Blood Glucose Meter

⚠NOTE:
Make sure the Touch-In® Plus Blood Glucose Test Strips are not expired. Check the test strip expiration date on the box and the test strip bottle.The month printed refers to the end of the month.

Step 1: Locate the code card () in the package of test strip.

Step 2: Verify that the code number on the code card matches the code number on the test strip package

Step 3: Insert the code card with the code number facing up firmly and completely into the code card port on the backside of the meter.

Step 4: Obtain a test strip () and insert the strip into the test strip holder located at front bottom of the meter. The meter will turn on with a beep sound. Close the test strip bottle immediately after you take out a strip.

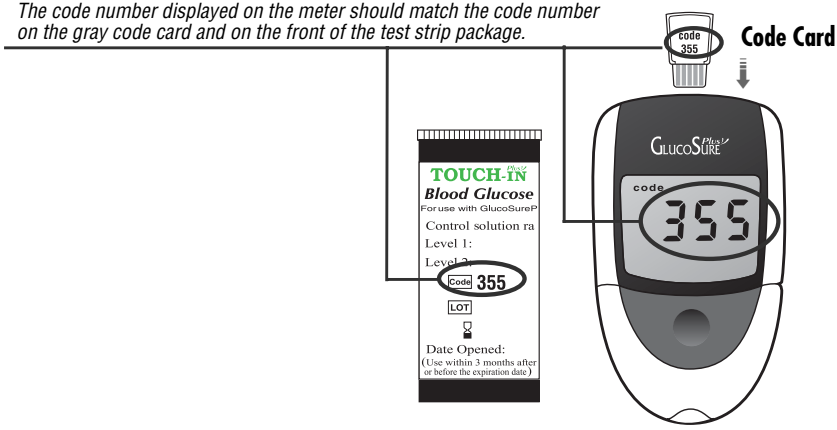
Step 5: A 3-digit code number will display on the meter screen. Verify the code number on the screen with that on the code card and on the test strip package. All three sets of numbers should be the same.

⚠NOTE:

1. The code card found in the test strip package is for use with that particular package only. Test strips from different packages and other brands of test strip may produce inaccurate results.
2. Make sure the three sets of numbers from the meter display screen, the code card, and the test strip package match.

3. Re-coding needs to be done when the battery is replaced or a new package of test strip is opened for use.

The code number displayed on the meter should match the code number on the gray code card and on the front of the test strip package.



Performing a Blood Glucose Test

Materials you will need:

- A brand new Touch-In® Plus Blood Glucose Test Strip
- Your GlucoSure® Plus Blood Glucose Meter

⚠IMPORTANT:

1. Do not use test strip that has expired. Check the expiration date ⌛ that is printed on the test strip bottle and box.
2. Use each test strip immediately after removing it from the bottle.
3. After removing a test strip from the bottle, replace the bottle cap immediately and close it tightly.
4. Do not use wet, bent, or scratched test strip.
5. Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place ☀.
6. Record the "date opened" on the test strip bottle label when you first open it. After 3 months since first opened date, discard the bottle and any remaining test strip.

Step 1: After you have performed the previous section, "**Coding the Meter**," the meter will now self-test the environment temperature. If the temperature is below or above operation range, the screen will display the flashing symbol of thermometer "  ". When the temperature is within the testing range of 18°C to 38°C 

(64°F to 100°F), the screen will show a symbol "" and the meter is now ready for testing.

⚠**IMPORTANT:**

1. Each time the GlucoSure® Plus Blood Glucose Meter is used, the current code will appear on the display screen when turned on. Verify that the code displayed on screen matches the code number printed on the test strip package before testing. The code needs to be set only once for each package of test strips. The meter will memorize the code until it is changed. Code number displayed on screen not matching the code number printed on the test strip package will create an inaccurate test result.
2. If the screen shows "Code----" (meaning that the Meter is not coded), or if the code number on the screen does not match the code number on the test strip package, refer to Chapter 3, p.20 "**Coding the Meter**"  .

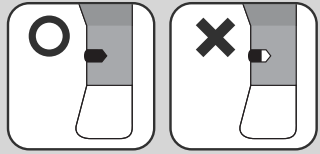
⚠NOTE:
If the temperature is outside of the operating range, the meter needs to be moved to an area that is within the meter's operating range of 18°C to 38°C (64°F to 100°F) and allow 10 to 15 minutes for it to reach the new temperature before use. Measurement outside the temperature range will affect accuracy of test result.

Step 2: Wash hands with soap and warm water and dry thoroughly.

Step 3: Obtain a drop of blood using your lancing device, Consult your healthcare professional for the proper technique of using a lancing device.

Step 4: Apply the blood to the protruding reaction zone located at the curved edge of the test strip. When the reaction zone has filled completely the meter will beep, indicating that blood has been received by the test strip.

⚠NOTE:
- **DO NOT** touch the target area of the test strip.
- **DO NOT** smear the blood drop onto the target area.



- **DO NOT** add or apply a second drop of blood. This may cause false result.
- **DO NOT** proceed testing if the yellow window is not full of blood sample. Insufficient blood sample may cause inaccurate test result.

Step 5: The meter screen will display timing bars "-----". The bars will flash and gradually diminish for countdown.

Step 6: After the timing bars disappear (approximately 10 seconds), the screen will display test result. Record the test result in the glucose log book. The test result is also automatically stored into the Meter's memory, refer to Chapter 5, p.30 "**Using Meter Memory**" 📖 . The meter will automatically turn off after the Test Strip is removed or after 3 minutes.

⚠**CAUTION:**
- The used lancet and test strip are biohazard materials which should be disposed of properly to avoid injury or contamination.
- When the yellow window is not filled with blood sample, the meter will not start measuring blood glucose level (no beeping sound). When this happens, discard the test strip and retest with a brand new test strip.

Chapter 4. Understanding Your Blood Glucose Test Results

Blood glucose levels fluctuate naturally, causing test results to vary over time and can also be affected by several factors. Some of which include but are not limited to the following:

- The time of day the test is performed.
- The food you eat.
- Activities you perform.
- The insulin and other medications you take.

If abnormally high or low readings persist, contact your healthcare professional.

Abnormal Blood Glucose Readings

Abnormal blood glucose level above 250 mg/dL (above 13.9mmol/L) or below 50 mg/dL (below 2.8 mmol/L) may indicate a potential serious medical condition. If your blood glucose reading does not seem to reflect how you feel, perform the **Quality Control Testing** on p.13 to ensure your system is working properly. After you have performed the control solution test, repeat your blood glucose test again, see Chapter 3., **Performing a Blood Glucose Test**, p.23 . If abnormally high or low readings appear again, contact your physician for advice on what action should be taken.

Always record your results in logbook. The logbook assists in keeping a record of blood glucose results, along with information on food intake, exercise, and medication.

Recent Diabetes Findings

In 1993 the National Institute of Health concluded an extensive long-term study of people with Type I diabetes, the Diabetes Control and Complications Trial (DCCT) found that by keeping your blood glucose close to the level of people without diabetes you could reduce the risk of complications involving the eyes, kidneys, and nervous system by approximately 60%.

What This Means for You

Frequent blood glucose testing is the best means you have for keeping track of how well you are doing with the factors that can affect your diabetes: medication, diet, exercise, and stress management. Blood glucose test results can also tell you whether your diabetes is changing in ways that might require an adjustment to your treatment plan. How often you need to test your blood glucose is different from person to person. Your healthcare professional will guide you. After deciding when and how often you should test, it is important that you make testing part of your daily routine.

References

1. American Diabetes Association position statement on the Diabetes Control and Complication Trial (1993).
2. Clarke, W.L., et al.: Diabetes Care, 1987, Vol.10, No. 5, p. 628-662
3. Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast, April 1988, p.49-51
4. Wickham, N. W.R., et al: Practical Diabetes, 1986, Vol. 3, No. 2, p.100
5. Cohen, F.E., et al: Diabetes Care, 1986, Vol. 9, No. 3, p. 320-322

Chapter 5. Using Meter Memory

Your GlucoSure® Plus Blood Glucose Meter automatically stores 10 test results. When more than 10 test results have been performed, the oldest result will be dropped from memory each time a new result is added. When the test results are recalled from memory, the most recent result is always displayed first.

To recall the results from memory:

Step 1: Press the push button to turn on the Meter. The screen will display the latest test result stored in memory.

Step 2: Repeat pressing the push button for reviewing further test results in memory.

Chapter 6. Caring for the Meter

Cleaning the Meter

Your GlucoSure® Plus Blood Glucose Meter does not require special cleaning. If the meter gets dirty, use a moist (NOT WET) lint-free cloth dampened with a mild detergent.

⚠NOTE:

1. **DO NOT** get water inside the GlucoSure® Plus Blood Glucose Meter. Never immerse the meter or hold it under running water.
2. **DO NOT** use glass cleaners or household cleaners on the meter.
3. **DO NOT** try to clean the test strip holder.

⚠Storage and Precautions:

- Handle the meter with care- severe shock, such as dropping the meter, could damage the electronics.
- The meter and the test strips are designed to be used within the temperature ranges between 18°C to 38°C (64°F to 100°F) 

.
- Avoid leaving the meter in extremely hot or cold place, such as near a heat source or

in an extremely hot or cold car.

- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Never immerse or hold the meter under running water.
- Always replace the top bottle cap immediately after removing a test strip and make sure it is closed tightly.
- DO NOT take the GlucoSure® Plus Meter apart. If there are technical problems or questions in use of the meter, call the authorized dealer.

Chapter 7. Changing the Battery

The GlucoSure® Plus Blood Glucose Meter operates on one 3V lithium coin cell battery (CR2032). When the display screen shows a flashing symbol of " ⊟ " , this indicates the battery is low and should be replaced as soon as possible.

⚠NOTE:
To save battery power, the GlucoSure® Plus Blood Glucose Meter will turn itself off after 3 minutes of non-use. All results stored in memory will be saved even if the meter shuts off automatically.

To replace the battery:

Step 1: Open battery compartment cover on backside of the meter.

Step 2: Remove the old battery and replace with a new 3V Lithium coin cell battery (CR2032).

Step 3: Replace the battery compartment cover.

Chapter 8. Message Interpretations & What to Do

If there is a problem with the way you are performing a test or if there is a problem with your GlucoSure® Plus Blood Glucose Meter, any of the following messages may appear on the meter screen.

If you have further questions after reviewing these messages, call our authorized dealer.

Message	Meaning	What To Do
“code----”, then the meter shuts off in 3 seconds.	The meter has not been coded with a code card.	Code your Meter with a Touch-In® Plus Code Card, see Chapter 3, p.20 "**Coding the Meter**."
" ⊟ "	The battery in the meter is running out of power.	Replace the battery. See the instructions on Chapter 7, p.33 "**Changing the Battery**" 🕮 .

Message	Meaning	What To Do
"  "	The temperature of your meter, the surrounding air, or the test strip is outside of system's operation range.	The meter needs to be moved to an area that is within the system's operation range of 18°C to 38°C  (64°F to 100°F), and wait for 10~15 minutes to let the meter adjust to the new temperature.
Code number and flashing "  " displaying after blood sample is applied.	Not enongh blood sample is applied to the yellow reaction zone.	First check if the yellow reaction zone is filled with blood sample, if it is not, discard the test strip from the meter and retest with a new test strip.
LO	The blood glucose result is lower than 30mg/dL (1.7mmol/L)	Check using right code card and new test strip, and the blood volume is suitable for applying, then repeat the test to confirm the test result. If it reads LO again, contact your healthcare professional.

Message	Meaning	What To Do
HI	The blood glucose result is higher than 550mg/dL (30.6mmol/L)	Check using right code card and new test strip, and the blood volume is suitable for applying, then repeat the test to confirm the test result. If it reads HI again, contact your healthcare professional.
" ☹ "	1. A used test strip is inserted. 2. The meter does not function properly.	Remove and discard the used test strip ⊗, then perform the "**Monitor Checker Test**" on p.12 📖 . If the problem persists, contact our authorized dealer for service.

If you are unable to correct the problem after following the What To Do procedures, call our authorized dealer in your country or contact your healthcare professional with questions and concerns.

Chapter 9. Performance Evaluations

The performance evaluation is determined in both clinical and laboratory settings.

Accuracy

Accuracy describes how well the readings from a testing system (meter and test strips) agree with the readings from an internationally accepted reference system (laboratory glucose analyzer) and are performed according to an internationally recognized standard. The accuracy of the GlucoSure® Plus Blood Glucose Monitoring System is referenced to the YSI 2300 Glucose Analyzer and the evaluation studies were performed according to ISO/ DIS 15197 guidelines.

A total of 127 fresh capillary blood specimens from different subjects were collected and tested with the GlucoSure® Plus Blood Glucose Monitoring System. The specimens ranged from 39 mg/dL to 496 mg/dL, as measured by the YSI 2300 comparative method. Linear regression data showed that the GlucoSure® Plus Blood Glucose Monitoring System correlates well with the YSI 2300 Glucose Analyzer.

Clinical Site Studies	
Number of Samples:	127
Range:	39 mg/dL to 496 mg/dL
Slope:	1.037
Intercept:	-4.68 mg/dL
Correlation Coefficient:	0.988

Precision

Precision describes the variation between readings in the test system. A test system with little variation is defined as precise. A study was conducted with the GlucoSure® Plus Blood Glucose Monitoring System using five heparinized blood specimens with concentrations ranging from 43 mg/dL to 378 mg/dL. Multiple replicates (n=20) were tested using multiple GlucoSure® Plus Blood Glucose meters and one lot of Touch-In® Plus Blood Glucose Test Strips. The following precision results were obtained.

Individual Use Method					
Number of Readings:	20	20	20	20	20
Average (mg/dL):	43	84	120	198	378
S.D. (mg/dL):	2.5	2.5	3.8	4.7	11.0
C.V%:	5.8	3.0	3.2	2.4	2.9

For more information on the Touch-In® Plus Blood Glucose Test Strips, please refer to the packaging insert found in each box of test strips.

Chapter 10. Specifications

Test Strips:	Touch-In® Plus Blood Glucose Test Strips
Test Range:	30 - 550 mg/dL (1.7 - 30.6 mmol/L)
Blood Source:	Capillary whole blood
Hematocrit Range:	30-55%
Display Type:	Large LCD screen
Memory:	10 blood glucose test result
Dimension:	100L x 58W x 21H (mm)
Weight:	64g
Power Supply:	1 x 3V Lithium coin cell battery (CR2032)
Operating Temperature:	18 °C to 38°C (64°F to 100°F)
Relative Humidity:	Less than 85%
Storage Condition:	4 °C to 55°C (39.2°F to 131°F) for meter 4 °C to 30°C (39.2°F to 86°F) for test strip

⚠NOTE:
For more information regarding the test strips, see the test strip package insert found in each box of test strips 🕮 .

Applied Product Standards:

ISO/DIS 15197	IEC 61010-1
IEC 60601-1	EN 60601-1
EN 61010-1	EN 60601-1-2
EN 61326	

Chapter 11. Supplies

Part Number	Product Name
S6031	GlucoSure® Plus Blood Glucose Monitoring System
S5635103	Touch-In® Plus Blood Glucose Test Strips 100's
S5635066	Touch-In® Plus Blood Glucose Test Strips 50's
S5635067	Touch-In® Plus Blood Glucose Test Strips 2 x 25's
65235010001	Lancing Device
80050000003	Lancets 50's
S5800012	Contrex™ Plus Glucose Control Solution (L1 &L2)

Chapter 12. Symbols Used in this Manual


(EXP) Expiration date (use by last day of month)


(LOT) Batch code

Temperature limitations


Consult instructions for use

In vitro diagnostic device


Caution / warning, consult accompanying documents

Product code number


Keep away from sunlight/direct light


Do not re-use

Chapter 13. Product Warranty

The GlucoSure® Plus Blood Glucose Meter is guaranteed to be free of defects in workmanship and materials under normal use for a period of five (5) years from the date of purchase to the consumer.

The liability of Apex Biotechnology Corp is limited to repair or replacement and in no event shall Apex Biotechnology Corp be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the Apex Biotechnology Corp authorized dealer responsible for the sale of the system.

The warranty applies only to the original purchaser of the system.