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## Chapter 1. About Your MultiSure™ Blood Glucose and Uric Acid Monitoring System

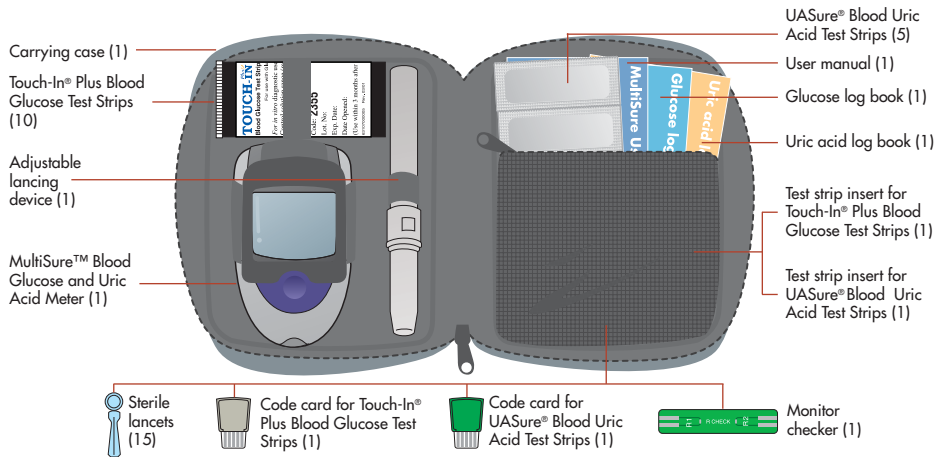
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You have chosen a unique diagnostic tool to help monitor your blood glucose (blood sugar) and uric acid levels in your body. All of the information that will be needed to use and maintain your MultiSure™ Blood Glucose and Uric Acid Monitoring System is included in this manual. Read it carefully before using the system.

Your MultiSure™ Blood Glucose and Uric Acid Monitoring System utilizes biosensor technology to provide an easy and precise way of measuring the level of glucose (blood sugar) or uric acid in capillary blood from the finger at specific points in time. This portable battery operated meter is intended for use outside the body (in vitro diagnostic use) and provides important information relating to blood glucose and blood uric acid control. Your MultiSure™ Blood Glucose and Uric Acid Monitoring System is designed for both self-testing by an individual and for use by healthcare professionals.

## Contents of Kit

The MultiSure™ 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.


## MultiSure™ Blood Glucose and Uric Acid 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 7, p.45 “Using Meter Memory” for details .
- 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 number of test strips. Gray code card is for Touch-In® Plus Blood Glucose Test Strips and green code card is for UASure® Blood Uric Acid Test Strips. A new code card is packaged with each new bottle of test strips.

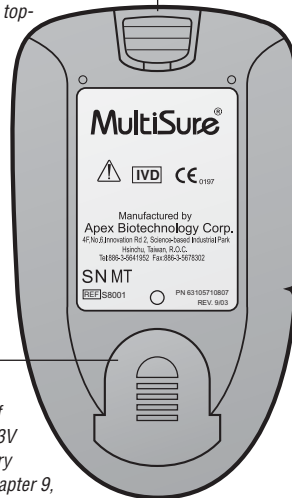


**Monitor Checker**

Used to confirm that the MultiSure™ Meter is functioning properly. Refer to Chapter 2, p.13 "Monitor Checker Test" ⓘ for details.

**Code Card Port**

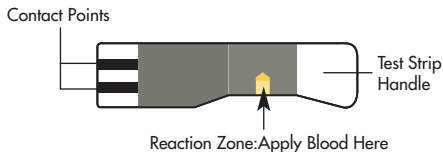
Insertion site for the code card. Located at the top-back of the meter.



**Battery Compartment**

Located on the back of the meter. Holds one 3V Lithium coin cell battery (CR2032). Refer to Chapter 9, p.48 "Changing the Battery" ⓘ .

## Touch-In® Plus Blood Glucose Test Strip

**Contact Points**


Sense the position and orientation of the test strip.

**Test Strip Handle**

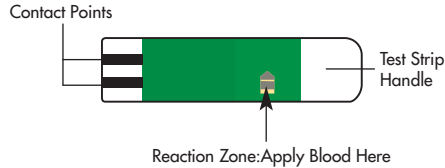
The only area to be touched when handling the Test Strip.

**Reaction Zone**

The area where the blood sample or Control Solution is applied.

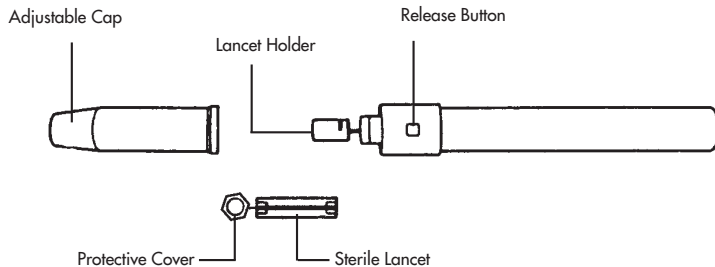
The MultiSure™ Meter is designed specifically to detect glucose in whole blood with the Touch-In® Plus Test Strip only. The Test Strips come in a moisture-proof, light-protected bottle . It is important that the bottle is kept well sealed at all times and the cap is replaced immediately after a strip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

## UASure® Blood Uric Acid Test Strips




The UASure® Blood Uric Acid Test Strip is designed specifically to detect uric acid in whole blood with the MultiSure™ Meter only. The UASure® Blood Uric Acid Test Strips are individually packaged in aluminum foil for protection and storage. Please store the unused test strips in a cool, dry place or in your wallet and only take them out as needed.

## Adjustable Lancing Device and Lancets




The MultiSure™ kit includes an adjustable 5 setting lancing device and sterile lancets for your comfort and protection. You can adjust the puncture depth of your lancing device according to the thickness of your skin, from the lightest (1) to the deepest (5).

## Contrex™ Plus Glucose Control Solution (Optional)

Standard glucose concentration solution specifically designed to be used with Touch-In® Plus Blood Glucose Test Strips and is required to perform the "Contrex™ Plus Glucose Control Solution Test" in Chapter 3, p.23  to make sure the Test Strips and the Meter are working together properly, practice test procedure, and when using a new lot of Touch-In® Plus Blood Glucose Test Strips.



## UASure® Uric Acid Control Solution (Optional)

Standard uric acid concentration solution required to perform the "UASure® Uric Acid Control Solution Test" in Chapter 5, p.38  to make sure the Test Strips and the Meter are working together properly, practice test procedure, and when using a new lot of UASure® Blood Uric Acid Test Strips .



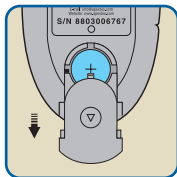
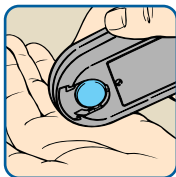
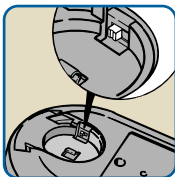
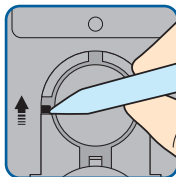
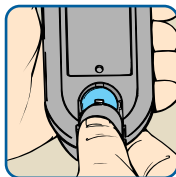
## Chapter 2. Before Testing

### Changing Unit of Measurement

Your MultiSure™ Meter can display test results in either mg/dL or mmol/L for glucose measurements, and mg/dL or  $\mu\text{mol/L}$  for uric acid measurements. The factory setting for both measurements is mg/dL. Consult your healthcare professional before changing the unit of measurement.

#### Material you will need:

- Your MultiSure™ Meter

**1****2****3****4****5**

**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 displaying the measurements at mg/dL (both glucose and uric acid), or push the switch upwards for displaying the measurements at mmol/L (for glucose) and  $\mu\text{mol/L}$  (for uric acid).
- Step 5:** Install the battery, and replace the battery cover.

### Monitor Checker Test

The Monitor Checker Test will help ensure that the electronics in your MultiSure™ 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 MultiSure™ Meter
- A gray code card for Touch-In® Plus Test strips(  ) or a green code card for the UASure® Blood Uric Acid Test Strips(  )

- Step 1:** Insert either a gray code card for the Touch-In® Plus Test strips(  ) or a green code card for the UASure® Blood Uric Acid Test Strips(  )

into the code card port located at the top-back side of the meter.

**Step 2:** Insert the Monitor Checker (R1 end) into the test strip holder until you hear a "beep."

**Step 3:** The meter will now go into self-diagnostic mode and if the display screen shows "OK" than your meter is functioning properly. If the display screen shows "ntOK" then repeat the testing procedure. If "ntOK" continues to appear on the display screen, refer to Chapter 12, p.55 "**Messages Interpretation & What to Do**" .

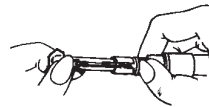
**Step 4:** Repeat the testing procedures steps 1 through 2 on the R2 end of the Monitor Checker.

## Inserting Lancets Into Lancing Device

### Materials you will need:

- A sterile lancet
- Lancing device (included in kit)

**Step 1:** Take out the lancing device and a new lancet. Unscrew the adjustable cap of the lancing device and insert the lancet into the lancet holder and push down firmly until it is fully

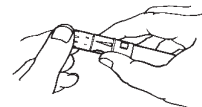


seated.

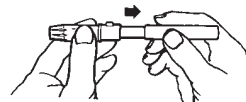
**Step 2:** Twist the protective cover off from the lancet, then screw clockwise the adjustable cover back onto the lancing device.



**Step 3:** Adjust the puncture setting located on the adjustable cap for the puncture depth level (1 is the lightest and 5 is the deepest).



**Step 4:** With one hand holding the adjustable cap, the other hand pull back the lancing device until you hear a click sound. The lancing device is now ready for blood sampling.




**⚠ IMPORTANT:**

Use a new sterile lancet every time you test to avoid cross contamination. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.



## Chapter 3. Glucose Testing

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### Coding the meter


The MultiSure™ Meter uses the Touch-In® Plus Blood Glucose Test Strips for testing glucose. When using the Touch-In® Plus Blood Glucose Test Strips, you must also "code" the meter before you can begin testing on your MultiSure™ Meter. Coding is a process of programming your meter to the new box of test strips and to ensure accurate test results. The code card for glucose testing is gray in color (  ) and is packaged along with each box of Touch-In® Plus Blood Glucose Test Strips.

#### **Materials you will need:**

- A gray code card for the Touch-In® Plus Blood Glucose Test Strips (  )
- A Touch-In® Plus Blood Glucose Test Strip (  )
- Your MultiSure™ Meter


#### **NOTE:**

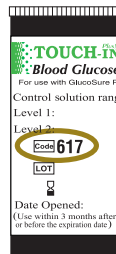
Make sure the Touch-In® Plus Blood Glucose Test Strips are not expired. Check the test strip expiration date on the box and the test strip bottle. The month printed refers to the end of that month.

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

**Step 2:** Verify the code number on the gray 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 (  ) from the test strip bottle and insert the test strip into the test strip holder located at front bottom of the meter. Inserting the test strip into the test strip holder will automatically power on the meter.



 **NOTE:**

Close the test strip bottle immediately after you take out a test strip.

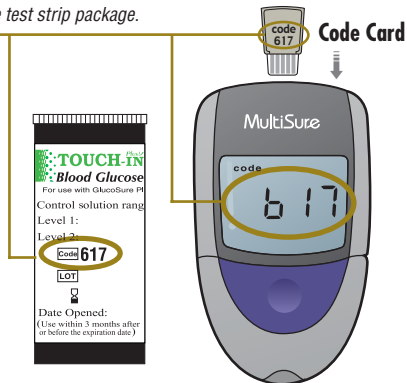
**Step 5:** A 3-digit code number will display on the center of the display screen and the

words "GLU" will appear on the upper right corner of the display screen. Your meter is now in glucose testing mode. Verify the code number on the center of the display screen matches with the code number on the code card and on the test strip package. The three sets of numbers (in this example) should be the same.

*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.*

**NOTE:**

1. Make sure the code card is securely lodged into the code card port on the backside of the meter.
2. The gray code card found in Touch-In<sup>®</sup> Plus Test Strip package is for use with that particular package only. Test strips from different packages of Touch-In<sup>®</sup> Plus Test Strip and other brands of



test strip may produce inaccurate results.

3. Make sure the three sets of numbers from the meter display screen, the code card, and the test strip package matches.

 **NOTE:**


Re-coding needs to be done , when a new package of test strip is opened for use, or when changing testing type.

## Performing a Blood Glucose Test


### **Materials you will need:**



- A brand new Touch-In<sup>®</sup> Plus Blood Glucose Test Strip
- Your MultiSure<sup>™</sup> 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 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. 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 operation range, the screen will display "tLO", and "tHI" if the temperature is above operation range. 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 ready for use.


 **IMPORTANT:**

1. Each time the MultiSure™ Meter is used, the current code and testing type (**GLU** for Glucose, **UA** for Uric Acid) will appear on the display screen when turned on.

Verify that the code displayed on screen matches the code number on the package of test strip and the testing type matches the type of test strip you are using before testing. The meter will memorize the code until it is changed. The code number on the meter screen not matching the code number 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.16 "**Coding the Meter**"  .

 **NOTE:**

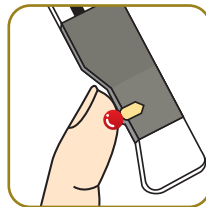
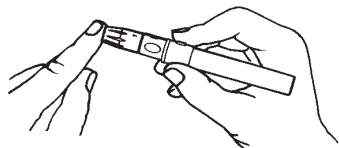
If the temperature is outside of the operating range, the meter needs to be moved to an area that is within the meter's operating range of 18°C to 38°C  (64°F to 100°F) and allow 10 to 15 minutes for it to reach the new temperature before use. Measurement outside the temperature range will affect accuracy 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, refer to Chapter 2, p.14 "**Insert Lancets into Lancing Device**"  .

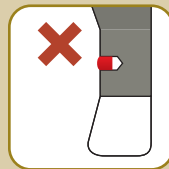
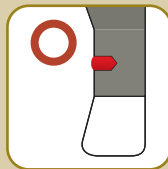
Consult your healthcare professional for the proper technique of using a lancing device.


- 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 7, p.45 "Using Meter Memory" )  . The meter will automatically turn off after the test strip is removed or after 3 minutes.

 **CAUTION:**

- The used lancet and strip are biohazard materials, which should be disposed of properly to avoid injury or contamination.

### Contrex™ Plus Glucose Control Solution Test:

Perform the Contrex™ Plus Glucose Control Solution Test 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 MultiSure™ Meter and Test Strip 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 test strip insert for operation ranges).
- Practice the test procedure.


Two levels of Contrex™ Plus Glucose Control Solutions are available - Level 1 and Level 2. Each level tests a different range of glucose concentration.


**⚠ IMPORTANT:**

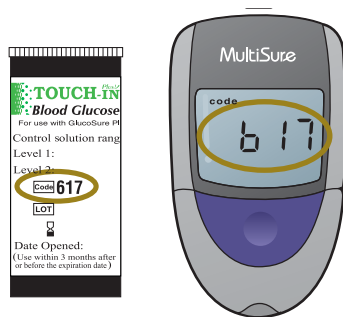
- The acceptable range for the control solution is listed on the package of test strips.
- Use only the Contrex™ Plus Glucose Control Solutions with the Touch-In® Plus Blood Glucose Test Strips. Other brands of glucose solution may produce inaccurate result.
- Always check the expiration date ⏰ . **DO NOT** use control solutions if expired.
- Newly opened bottle of control solution must be marked with the date opened; discard any unused control solution three months after opening or expiration date ⏰ .
- Control solutions should be kept at room temperature  $15^{\circ}\text{C}$  to  $30^{\circ}\text{C}$  . **DO NOT FREEZE.**

- If a control solution test is not within the expected range that is printed on the test strip package, **DO NOT** use the System to test. Repeat the test until a control solution test performs within the expected range. If the results continue falling outside the expected range, call the authorised 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.
- **DO NOT** smear the control solution with the tip of the control solution bottle.
- 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
- A gray code card for the Touch-In® Plus Blood Glucose Test Strip (  )
- Monitor checker (included in kits)
- Your MultiSure™ Meter

- Step 1:** Perform the Monitor Checker Test, refer to Chapter 2, p.13 "**Monitor Checker Test**" .
- Step 2:** After the display screen of the meter showing "OK," the screen will then display the current code number being used. Verify that code number on screen is the same as the code number printed on the bottle label and remove a test strip from the test strip bottle.



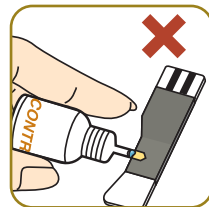
 **IMPORTANT:**

1. Do not use test strip that has expired. Check the expiration date  that is printed on the test strip bottle and 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 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. After 3 months since first opened date, discard the bottle and any remaining test strip.


**Step 3:** Insert a brand new Touch-In® Plus Test Strip into the Test Strip Holder of the Meter. The screen will show "ctrl."

**Step 4:** When the screen shows a symbol 📧 , apply a drop of Contrex™ Plus Glucose Control Solution Level 1 control solution (solution with **green** bottle cap) on top of the yellow reaction zone of the test strip. Do not use the control solution to "touch" the protruding reaction zone at the center of the curved edge of the test strip.



**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 indicated 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 4. Understanding Your Blood Glucose Test Results



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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 **Contrex® Plus Glucose Control Solution Test** on p.23  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 Testing**, p.19  . 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
5. Wickham, N. W.R., et al: Practical Diabetes, 1986, Vol. 3, No. 2, p.100
6. Cohen, F.E., et al: Diabetes Care, 1986, Vol. 9, No. 3, p. 320-322

## Chapter 5. Uric Acid Testing Using MultiSure™ Meter

### Coding the meter



Just like testing for glucose on your MultiSure™ Meter; you must "code" the meter for each new package of uric acid test strips before using them. The code card for uric acid testing is green in color (  ) and is packaged along with each box of UASure® Blood Uric Acid Test Strips.

#### **Materials you will need:**

- A green code card for the UASure® Blood Uric Acid Test Strips (  )
- A UASure® Blood Uric Acid Test Strip (  )
- Your MultiSure™ Meter

#### **⚠ NOTE:**

Make sure the UASure® Blood Uric Acid Test Strips are not expired. Check the test strip expiration date on the box and the aluminum foil package. The month printed refers to the end of that month.

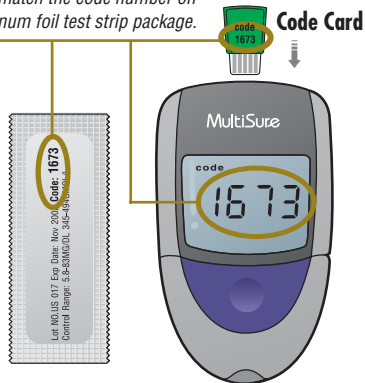
- Step 1:** Locate the green code card (  ) in the package of test strip.
- Step 2:** Verify the code number on the green code card matches the code number on the test strip package.
- Step 3:** Insert the code card with the code number facing up firmly and completely into the code card port on the backside of the meter.
- Step 4:** Obtain an aluminum foil packed test strip from the test strip package. Tear open the package and take out a uric acid test strip (  ). Insert the test strip into the test strip holder located at front bottom of the meter. Inserting the test strip into the test strip holder will automatically power on the meter.
- Step 5:** A 4-digit code number will display on the center of the display screen and the words "UA" will appear on the upper right corner of the display screen. Your meter is now in uric acid testing mode. Verify the code number on the center of the display screen matches with the code number on the code card and on the test strip package. The three sets of numbers (in this example) should be the same.

 **NOTE:**

1. Make sure the code card is securely lodged into the code card port on the

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

- backside of the meter.
- The green code card found in UASure® Blood Uric Acid Test Strip package is for use with that particular package only. Test strips from different packages of UASure® Blood Uric Acid Test Strip and other brands of test strip may produce inaccurate results.
  - Make sure the three sets of numbers from the meter display screen, the code card, and the test strip package matches.



**⚠ NOTE:**

Re-coding needs to be done , when a new package of test strips with a different code number is opened for use, or when changing testing type.



## Performing a Blood Uric Acid Test

Testing your blood for uric acid is very much the same as testing your blood for glucose.


### Materials you will need:



- A brand, new UASure® Blood Uric Acid Test Strip
- Your MultiSure™ Meter

### IMPORTANT:


1. Do not use test strip that has expired. Check the expiration date  that is printed on the test strip package and box.
2. Use each test strip immediately after removing it from the aluminum package.
3. Do not use wet, bent, or scratched test strips.
4. Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place .
5. Each time the MultiSure™ Meter is used, the current code and testing type (**GLU** for glucose, **UA** for Uric Acid) will appear on the display screen when turned on. Verify that the code displayed on screen matches the code number on the package of test strip and the testing type matches the type of test strip you are using before testing. The meter will memorize the code until it is changed. The

code number on the meter screen not matching the code number on the test strip package will create an inaccurate test result.


6. 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 5, p.32, "**Coding the Meter**"  .

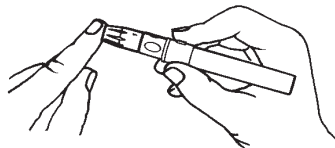
**Step 1:** After you have performed the previous section, "**Coding the Meter**," the meter will now self-test the environment temperature. If the temperature is below operation range, the screen will display "**tLO**", and "**tHI**" if the temperature is above operation range. When the temperature 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 ready for use.

 **NOTE:**

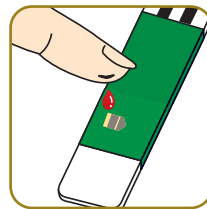
If the temperature is outside of the operating range, the meter needs to be moved to an area that is within the meter's operating range of 18°C to 38°C  (64°F to 100°F) and allow 10 to 15 minutes for it to reach the new temperature before use. Measurement outside the temperature range will affect accuracy 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, refer to Chapter 2, p.14 "Insert Lancets into Lancing Device"  . Consult your healthcare professional for the proper technique of using a lancing device.

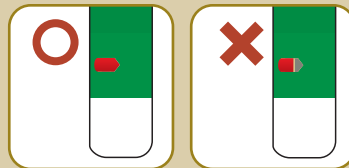


**Step 4:** Obtain a hanging blood drop and apply the blood to the yellow reaction zone on the top of the test strip. The meter will beep, indicating that blood has been applied to the test strip.




 **NOTE:**

- **DO NOT** proceed testing if the yellow window is not full of blood sample. Insufficient blood sample may cause inaccurate test result.
- **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.



**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 30 seconds), the screen will display test result. Record the test result in the uric acid log book. The test result is also automatically stored into the meter's memory, refer to Chapter 7, p.45 "Using Meter Memory"  . The meter will automatically turn off after the test strip is removed or after 3 minutes.

 **CAUTION:**

The used lancet and strip are biohazard materials, which should be disposed of properly to avoid injury contamination.



## UASure® Uric Acid Control Solution Test

### Perform the UASure® Uric Acid Control Solution Test when:

- You first get your meter, before performing a blood uric acid test.
- You first begin to use a new box of UASure® Blood Uric Acid Test Strips.
- You suspect your MultiSure™ Meter and test strip are not working properly.
- When your test strips have been exposed to extreme temperatures (  see test strip insert for operation ranges).

- The meter is dropped, damaged, or expose to liquids.
- Practice the test procedure.


### **IMPORTANT:**

- The acceptable range for the control solution is listed on the package of test strips.
- Use only the UASure® Uric Acid Control Solution.
- Always check the expiration date . **DO NOT** use control solution if expired.
- Newly opened bottle of control solution must be marked with the date opened; discard any unused control solution three months after opening or expiration date .
- Control solutions should be refrigerated after use. **DO NOT FREEZE.** When control solutions needs to be used again, allow it to stand under room temperature at least 30 minutes before use.
- If a control solution test is not within the expected range that is printed on the test strip package, **DO NOT** use the System to test. Repeat the test until a control solution test performs within the expected range. If the results continue falling outside the expected range, call the authorised 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.
- **DO NOT** smear the control solution with the tip of the control solution bottle.
- Replace the bottle cap on the control solution bottle immediately after use.

### Materials you will need:


- UASure® Uric Acid Control Solution (optional items, contact our authorized dealer for purchasing information).
- A fresh, new UASure® Blood Uric Acid Test Strip
- Your MultiSure™ Meter

**Step 1:** Perform Monitor Checker Test to ensure the meter itself is functioning properly and enabling the meter not to store the control results into memory, refer to Chapter 2, p.13 "**Monitor Checker Test**"  .

### **NOTE:**


When performing the UASure® Uric Acid



Control Solution Test, make sure the green code card for the UASure® Blood Uric Acid Test Strip (  ) is inserted at the code card port located at the top back side of the meter.


**Step 2:** After the display screen of the meter showing "OK," the screen will then display the current code number being used. Verify that code number on screen is the same as the code number printed on the test strip package and remove a test strip from the aluminum foil package.

 **IMPORTANT:**


1. Do not use test strip that has expired. Check the expiration date that is printed on the test strip package.
2. Use each test strip immediately after removing it from the aluminum package.
3. Do not use wet, bent, or scratched test strips.
4. Keep away from direct sunlight and heat. Store the test strip in a dry, cool place .

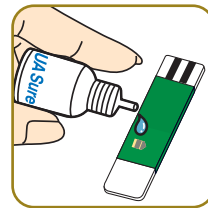
**Step 3:** Insert a brand new UASure® Blood Uric Acid Test Strip into the test strip holder

of meter. The screen will show "ctrl."

**Step 4:** When the screen show a symbol , apply a drop of UASure® Uric Acid Control Solution on the yellow reaction zone of the test strip.

**Step 5:** The display screen will shows 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 control range indicated 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  .



 **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 6. Understanding Your Uric Acid Test Results

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Uric acid in your body may fluctuate over time. Your test results may also vary because of several factors. Some of these factors include but are not limited to the following:

- The food you eat
- Activities you perform

Uric acid testing should be performed on fasting. If you feel your test results do not reflect how you feel, repeat the test. If abnormally high readings persist, contact your healthcare professional.

### Normal Blood Uric Acid Readings

**Target blood uric acid levels are as follows:**

**Male:** 3.5 ~ 7.2 mg/dL (208 ~ 428  $\mu$ mol/L)

**Female:** 2.6 ~ 6.0 mg/dL (155 ~ 357  $\mu$ mol/L)

Record your results in logbook. The logbook assists in keeping a record of blood uric

acid results, along with information on food intake, exercise, and medication.

## **High Blood Uric Acid Readings**

If your test results are higher than 7.2 mg/dL (above 428  $\mu\text{mol/L}$ ) for men, or 6.0 mg/dL (above 357  $\mu\text{mol/L}$ ) for women, than you may have a medical condition known as "hyperuricemia." Hyperuricemia patients are at risk of renal disease, and some patients may develop into a form of arthritis known as "gout."

### **NOTE:**

The MultiSure™ Meter is designed to perform and give accurate results at temperature range between 18°C to 38°C (64°F to 100°F). Operation outside the temperature range may affect the accuracy of the result.

## **Frequency of Testing**

How often you need to test your blood uric acid will vary according to your age, your diet, the medication you are taking, and your physical and emotional health. Your healthcare professional will assist you in deciding when and how often you should test. It is important that you follow their instructions.

## Chapter 7. Using the Meter Memory

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Your MultiSure™ Meter can automatically store 10 glucose test results and 10 uric acid test results. When the meter's memory becomes full, newly entered test result will replace the oldest result from the memory. 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 8. Caring for the Meter

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### Cleaning the Meter

Your MultiSure™ Meter do not require special cleaning. If the meter gets dirty, use a moist (NOT WET) lint-free cloth dampened with a mild detergent or isopropyl alcohol.


#### **NOTE:**

1. **DO NOT** get water inside the MultiSure™ 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.

#### **Precautions**


- DO NOT take the MultiSure™ meter apart. If there are technical problems or questions in use of the meter, call the authorised dealer.
- Handle the meter with care - severe shock, such as dropping the Meter, could damage the electronics.

## **Storage**

- 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 places, 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.

## Chapter 9. Changing the Battery

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The MultiSure™ Meter operates on one 3V Lithium coin cell battery. When the LCD screen displays a flashing symbol of "  ", this indicates the battery is low and should be replaced as soon as possible.

 **NOTE:**

To save battery power, the MultiSure™ 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 one new 3V Lithium coin cell battery.
- Step 3:** Re-place the battery compartment cover.

## Chapter 10. Performance Characteristics of MultiSure™ Meter and Touch-In® Plus Blood Glucose Test Strips

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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 is performed according to an internationally recognized standard. The accuracy of the MultiSure™ Blood Glucose and Uric Acid Monitoring System are referenced to the YSI 2300 Glucose Analyzer and the evaluation studies were performed according to ISO/ DIS 15197.

A total of 120 capillary blood samples from different subjects were collected using collection tubes with anticoagulants. The samples were then allowed to stand until the mean glucose value within the samples were lowered to < 60 mg/dL. Afterwards, the samples were spiked with glucose to achieve different concentration range from 43 mg/dL to 465 mg/dL. The prepared samples were then tested on the MultiSure™ Blood Glucose and Uric Acid Monitoring System and compared to the readings from YSI 2300

Glucose Analyzer. Linear regression data showed that the MultiSure™ Blood Glucose and Uric Acid Monitoring System correlates well with the YSI 2300 Glucose Analyzer. Data are as follows:


Clinical Site Studies	
Number of Samples:	120
Range:	43 mg/dL to 465 mg/dL
Slope:	1.034
Intercept:	-3.07 mg/dL
Correlation Coefficient:	0.989

### **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 MultiSure™ Blood Glucose and Uric Acid Monitoring System using venous heparinized whole blood. The whole blood was spiked to provide samples at five different glucose concentrations ranging from 47 mg/dL to 369 mg/dL. Multiple replicates (n=20) were tested using

multiple MultiSure™ meters and one lot of Touch-In® Plus Blood Glucose test strips. The following precision results were obtained.

<b>Individual Use Method</b>					
Number of Readings:	20	20	20	20	20
Average (mg/dL):	47	92	123	203	369
S.D. (mg/dL):	1.9	3.1	2.9	5.1	11.9
C.V%:	4.1	3.4	2.4	2.5	3.2

 to information of the accuracy and the precision data in the package insert Touch-In® Plus Blood Glucose Test Strips for further details.

## Chapter 11. Performance Characteristics of MultiSure™ Meter and UASure® Blood Uric Acid Test Strips

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

### Accuracy


The accuracy of the MultiSure™ Blood Glucose and Uric Acid Monitoring System meets the manufacturer's criteria as stated in the specifications. A total of 24 venous blood samples from different subjects were collected using collection tubes with anticoagulants. The samples were spiked to achieve different concentration of uric acid ranging from 3.6 mg/dL to 19.0 mg/dL. The reference measurement was done on the EPAC 6140 (Eppendorf, Hamburg, Germany) using reagent from the UA Plus 1661868 kit (Roche Diagnostics, Postfach, Switzerland). Linear regression data showed that the MultiSure™ Blood Glucose and Uric Acid Monitoring System correlates well with the EPAC 6140 method. Data are as follows:

Clinical Site Studies	
Number of Samples:	96
Range:	3.6 mg/dL to 19.0 mg/dL
Slope:	0.9545
Intercept:	0.56 mg/dL
Correlation Coefficient:	0.9484

### **Precision**

A study was conducted with the MultiSure™ Blood Glucose and Uric Acid Monitoring System using venous heparinized whole blood. The whole blood was spiked to provide samples at four different uric acid concentrations ranging from 5.5 mg/dL to 18.0 mg/dL. Multiple replicates (n=20) were tested using multiple MultiSure™ meters and one lot of UASure® Blood Uric Acid test strips. The following precision results were obtained.



<b>Individual Use Method</b>				
Number of Readings:	20	20	20	20
Average (mg/dL):	5.5	9.8	13.9	18.0
S.D. (mg/dL):	0.4	0.2	0.2	0.5
C.V%:	4.1	2.2	1.2	2.7



 Refer to information of the accuracy and the precision data in the package insert of UASure<sup>®</sup> Blood Uric Acid Test Strips for further details.



## Chapter 12. Messages Interpretation & What to Do

If there is a problem with your meter or with the way you are performing a test, any of the following messages may appear on the meter display 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 monitor has not been coded with a code card.	Depending on which test you are performing; for glucose testing, see Chapter 3. For uric acid testing, see Chapter 5.
"  "	The battery in the meter is running out of power.	Replace the battery. See the instructions on Chapter 9, p.48 " <b>Changing the Battery</b> "  .

Message	Meaning	What To Do
"tLO"	The Testing environment is below the minimum operating range of 18°C (64°F)	The meter needs to be moved to an area that is within the meter's operating range, 18°C to 38°C  (64°F to 100°F), and wait for 10 ~ 15 minutes to let it adjust to the new temperature.
"tHI"	The Testing environment is above the maximum operating range of 38°C (100°F)	The meter needs to be moved to an area that is within the meter's operating range, 18°C to 38°C  (64°F to 100°F), and wait for 10 ~ 15 minutes to let it adjust to the new temperature.
LO	The blood glucose result is lower than 30mg/dL (1.7mmol/L) or the uric	Check using right code card and fresh test strip, and the blood volume is suitable for applying,

Message	Meaning	What To Do
	acid test result is lower than 3 mg/dL (179 $\mu$ mol/L)	then repeat the test to confirm the test result. If it reads <b>LO</b> again, contact your healthcare professional.
HI	The blood glucose result is higher than 550mg/dL (30.6 mmol/L) or the uric acid test result is higher than 20 mg/dL (1190 $\mu$ mol/L)	Check if you are using the right code card and fresh test strip, and the blood volume is suitable for applying, then repeat the test to confirm the test result. If it reads <b>HI</b> again, contact your healthcare professional.
“ ntOK“	A used test strip is inserted; or the meter does not function properly.	Remove and discard the used test strip.  <b>(Always use a new fresh test strip for each test.)</b> Perform " <b>Monitor Checker Test</b> " on Chapter 2, p.13  . If the problem persists, call for service.

If you are still 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 13. Specifications

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### **MultiSure™ Meter**

Operating Temperature:	18°C to 38°C (64°F to 100°F).
Relative Humidity:	Less than 85%
Calibration:	Lot specific external coding card
Memory:	10 results for glucose testing and 10 results for uric acid testing
Display Type:	Large LCD screen
Dimension:	100Lx58Wx21H (mm)
Weight:	64g (with battery Installed)
Power Supply:	1 x 3V Lithium coin cell battery
Storage condition:	4°C ~ 55°C (39°F ~132°F).


### **Touch-In® Plus Blood Glucose Test Strip**

Blood Source:	Capillary whole blood
Sample Volume:	3 µL
Assay Range:	30 - 550 mg/dL (1.7 - 30.6 mmol/L)
Hematocrit Range:	30 - 55%
Storage condition:	4°C ~ 30°C (39°F ~86°F).

## UASure® Blood Uric Acid Test Strips

Blood Source:	Capillary whole blood
Sample Volume:	6 µL
Assay Range:	3 - 20 mg/dL (179 - 1190 µmol/L)
Hematocrit Range:	35 - 50%
Storage condition:	4°C ~ 30°C (39°F ~86°F).

### **NOTE:**

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

## Applied Product Standards

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

## Chapter 14. Supplies

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<b>Part Number</b>	<b>Product Name</b>
S8001	MultiSure™ Blood Glucose and Uric Acid Monitoring System
S5635103	Touch-In® Plus Blood Glucose Test Strips 2 x 50's
S5635067	Touch-In® Plus Blood Glucose Test Strips 2 x 25's
S5635066	Touch-In® Plus Blood Glucose Test Strips 50's
U3601	UASure® Blood Uric Acid Test Strips 25's
65235010001	Lancing Device
80050000009	Lancets 50's
S5800012	Contrex™ Plus Glucose Control Solutions (L1 &L2)
U3500	UASure® Uric Acid Control Solution

## Chapter 15. Symbols Used in this Manual

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(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



Manufactured by

## Chapter 16. Product Warranty

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The MultiSure™ Blood Glucose and Uric Acid Monitoring System 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.'s authorized dealer responsible for the sale of the system.

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