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## Chapter 1. About Your UASure® Blood Uric Acid Monitoring System

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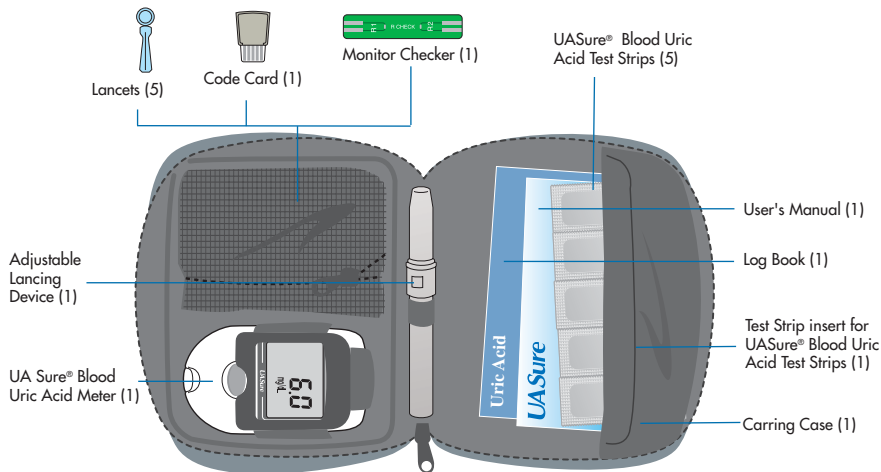
Thank you for choosing the UASure® Blood Uric Acid Monitoring System to help you manage your blood uric acid levels. All of the information that will be needed to use and maintain the UASure® Blood Uric Acid Meter is included in this manual. Read it carefully before using the system.

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

The UASure® Blood Uric Acid Monitoring System is intended for use outside the body (*in vitro* diagnostic use) and provides important information relating to blood Uric Acid control. Your UASure® Blood Uric Acid Monitoring System is designed for both individual self-testing and for use by healthcare professionals. Handicapped person and children way need assistance to use this device.

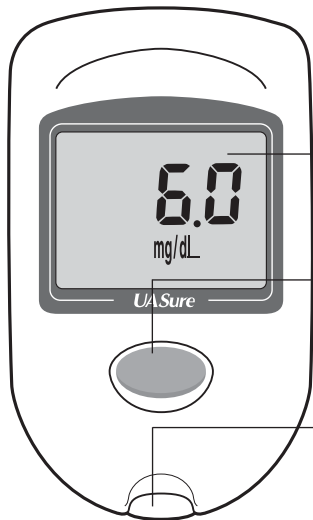
## Contents of Kit

The UASure® 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.


## UASure® Blood Uric Acid Meter



### Display Screen

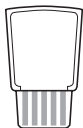
Large, easy-to-read window guides you through testing, displaying results, and error messages using simple words or symbols.

### Push Button

- Recalls test results in the memory. Refer to chapter 5, p.28 "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 of test strips. A new code card comes with each new package of test strips.




### Monitor Checker

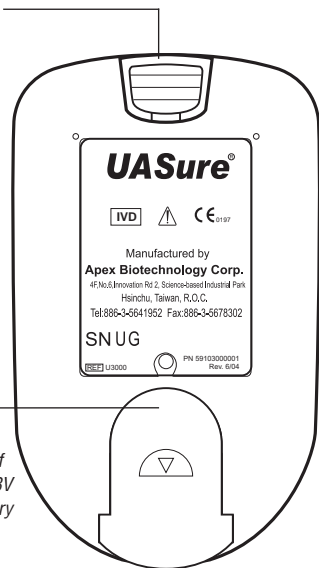
Used to confirm that the UASure® Blood Uric Acid Meter is functioning properly. Refer to Chapter 2, p.12 "Monitor Checker Test" for details .

### Code Card Port

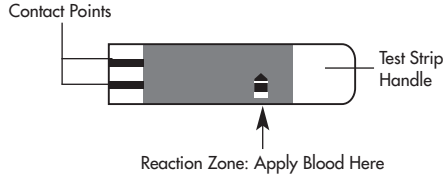
Insertion site for the code card. Located at the top-back of the meter.

### Battery Compartment

Located on the back of the meter. Holds one 3V Lithium coin cell battery (CR2032). Refer to Chapter 7, p.31 "Changing the Battery" .



## UASure® Blood Uric Acid 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.

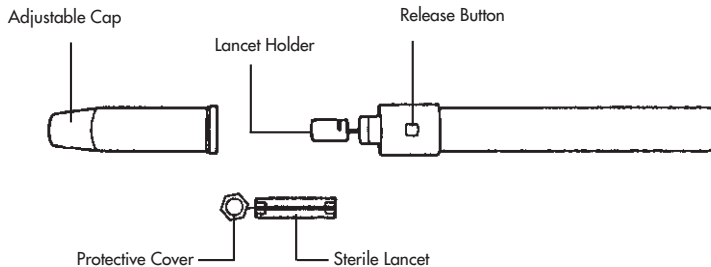
**Reaction Zone** The area where the blood sample or Control Solution is applied.

The UASure® Blood Uric Acid Meter is designed specifically to detect uric acid in whole blood with the UASure® Blood Uric Acid Test Strip only. The UASure® Blood Uric Acid Test Strips come in a moisture-proof, light-protected aluminum foil package





## Adjustable Lancing Device and Lancets



The UASure® 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).

## UASure® Uric Acid Control Solution (optional)



Standard uric acid 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 UASure® Blood Uric Acid Test Strips.

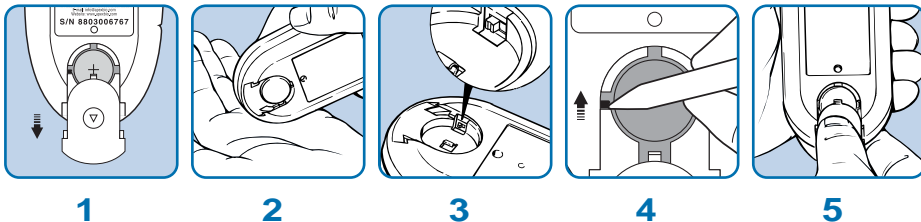
## Chapter 2. Before Testing

### Changing Unit of Measurement

Your UASure<sup>®</sup> Blood Uric Acid Meter can display test results in either mg/dL or  $\mu\text{mol/L}$ . The factory setting is mg/dL. Consult your healthcare professional before changing the unit of measurement.

#### Material you will need:

- Your UASure<sup>®</sup> Blood Uric Acid 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  $\mu\text{mol/L}$ .

**Step 5:** Install the battery, and replace the battery cover.

## **Monitor Checker Test**


The Monitor Checker Test will help ensure the electronics in your UASure® Blood Uric Acid 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 UASure® Blood Uric Acid 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 sad face " ☹ " then repeat the testing procedure. If " ☹ " continues to appear, refer to Chapter 8, p.32 "**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 uric acid test.
- You first begin to use a new package of UASure® Blood Uric Acid Test Strips.
- You suspect your UASure® Blood Uric Acid meter and test strips are not working properly.
- The blood uric acid results do not reflect how you feel.
- When your test strips have been exposed to extreme temperatures (  see UASure® Blood Uric Acid Test Strip Insert for operation ranges).
- 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.
- Replace the bottle cap on the control solution bottle immediately after use.


**Materials you will need:**


- UASure® Blood Uric Acid Control Solutions (optional items, contact our authorized dealer for purchasing information).
- A brand new UASure® Blood Uric Acid Test Strip.
- Your UASure® Blood Uric Acid 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 aluminum foil package of test strip.

** IMPORTANT:**


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

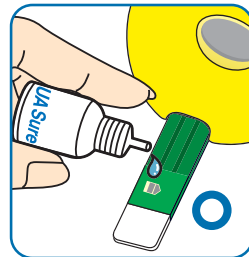
2. Use each test strip immediately after removing it from the aluminum foil package.
3. Do not use wet, bent, or scratched test strips.
4. Keep away from direct sunlight and heat. Store the test strip in a dry, cool place .

**Step 3:** Insert a brand new UASure® Blood Uric Acid Test Strip into the test strip holder of 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 , apply a drop of UASure® Blood Uric Acid Control Solution on top of the yellow reaction zone 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 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:**

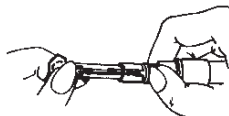
If the test result is not within the expected range, repeat the control solution testing. If the results continue falling outside the expected range, call our authorized dealer.

## Inserting Lancets Into Lancing Device

### Materials you will need

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

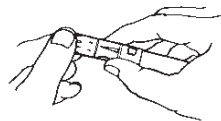
**Step 1:** Take out the lancing device and a new lancet. Unscrew the adjustable cap of the lancing device and insert the lancet into the lancet holder and push down firmly until it is fully seated.



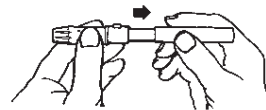
**Step 2:** Twist the protective cover off from the lancet, then screw clockwise the adjustable cover back onto the lancing device.



**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, pull back the lancing device with your other hand until you hear a click sound. The lancing device is now ready for blood sampling.



**⚠ IMPORTANT:**

1. Use only lancets that have been approved for use by your local health authority.
2. 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. Testing Your Blood Uric Acid Level

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### Coding the Meter



Before you can begin testing on your UASure® Blood Uric Acid 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 UASure® Blood Uric Acid Test Strips.

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

- A code card for the UASure® Blood Uric Acid Test Strips
- A brand new UASure® Blood Uric Acid Test Strip
- Your UASure® Blood Uric Acid 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 test strip package. The month printed refers to the end of the month.

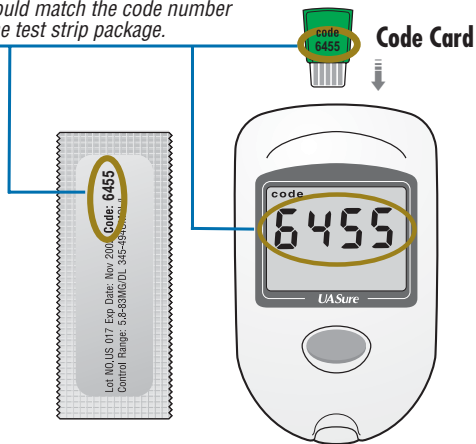
- Step 1:** Locate the code card (  ) in the package of test strip.
- Step 2:** Verify that the code number on the code card matches the code number on the test strip package.
- Step 3:** Insert the code card with the code number facing up firmly and completely into the code card port on the backside 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.
- Step 5:** A 4 -digit code number will display on the meter screen. Verify the code number on the screen with that on the code card and that 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 a new package of test strip is opened for use or when changing battery.

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







## Performing a Blood Uric Acid Test

### Materials you will need:


- A brand new UASure® Blood Uric Acid Test Strip
- Your UASure® Blood Uric Acid 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 strip.
4. Keep away from direct sunlight and heat. Store the test strip package in a dry, cool place .

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 tLO or tHI . When the temperature is within the testing range of 18°C to 38°C  (64°F to 100°F), the screen will show "  " and the meter is now ready for testing.


**⚠ IMPORTANT:**

1. Each time the UASure® Blood Uric Acid 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.19 "**Coding the Meter**" .

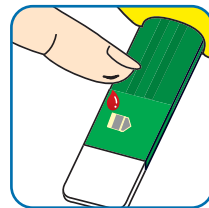
**⚠ NOTE:**

If the temperature is outside of the operating range, the meter needs to be moved to an area that is within its 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.

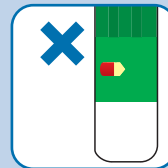
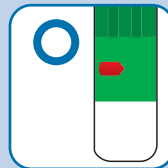
**Step 3:** Obtain a drop of blood using your lancing device, refer to Chapter 2, p.17 "**Inserting Lancets into Lancing Device**"  . Consult your healthcare professional for the proper technique of using a lancing device.

**Step 4:** Apply the blood to the yellow reaction zone on the top 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** 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 5, p.28 "**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.

## Chapter 4. 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)

## **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 maybe at risk of kidney complications such as kidney stones, and some may develop into a chronic form of arthritis known as "gout."

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.

## **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 5. Using Meter Memory

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Your UASure® Blood Uric Acid 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 your UASure® Blood Uric Acid 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 UASure® Blood Uric Acid 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 UASure® Blood Uric Acid 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.
- **DO NOT** take the UASure® Meter apart. If there are technical problems or questions in use of the meter, call the authorized dealer.

## Chapter 7. Changing the Battery

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The UASure® Blood Uric Acid Meter operates on one 3V lithium coin cell battery (CR2032) . 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 UASure® Blood Uric Acid 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.



### **IMPORTANT:**

Discard used battery according to your local regulation.

## 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 UASure® Blood Uric Acid 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 monitor has not been coded with a code card.	Code your Meter with a UASure® Plus Code Card, see Chapter 3, p.19 <b>"Coding the Meter."</b>
	The battery in the meter is running out of power.	Replace the battery. See the instructions on Chapter 7, p.31 <b>"Changing the Battery"</b>  .



Message	Meaning	What To Do
t LO	The temperature of the meter is below its operating range of <math><18^{\circ}\text{C}</math> (<math><64^{\circ}\text{F}</math>)	The meter needs to be moved to an area that is within the meter's operating range, <math>18^{\circ}\text{C}</math> to <math>38^{\circ}\text{C}</math> (<math>64^{\circ}\text{F}</math> to <math>100^{\circ}\text{F}</math>)
t HI	The temperature of the meter is above its operating range of <math>>38^{\circ}\text{C}</math> (<math>>100^{\circ}\text{F}</math>)	The meter needs to be moved to an area that is within the meter's operating range, <math>18^{\circ}\text{C}</math> to <math>38^{\circ}\text{C}</math> (<math>64^{\circ}\text{F}</math> to <math>100^{\circ}\text{F}</math>)
LO	The blood uric acid result is lower than <math>3\text{mg/dL}</math> (<math>179\ \mu\text{mol/L}</math>).	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 uric acid result is higher than 20 mg/dL (1190 $\mu$ mol/L).	Repeat the test to confirm the test result. If it reads HI again, contact your healthcare professional.
	<ol style="list-style-type: none"><li>1. A used test strip is inserted.</li><li>2. The meter does not function properly.</li></ol>	Remove and discard the used test strip  , then perform the " <b>Monitor Checker Test</b> " 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

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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 accepted reference system (laboratory analyzer). A total of 24 venous blood samples collected with anticoagulants from different subjects were performed at 4 different uric acid concentrations range with UASure<sup>®</sup> Meter and UASure<sup>®</sup> Blood Uric Acid Test Strips. The reference measurement was done on the EPAC 6140 (Eppendorf, Hamburg, Germany), included UA Plus 1661868 Kit (ROCHE, Postfach, Switzerland). The specimens ranged from 3.7 mg/dL to 19.2 mg/dL, as measured by the EPAC 6140 comparative method. Linear regression data from the combined studies compared well with results from the EPAC 6140 method.

Clinical Site Studies	
Number of Samples:	96
Range:	3.7 mg/dL to 19.2 mg/dL
Slope:	0.9856
Intercept:	0.32 mg/dL
Correlation Coefficient:	0.9519

## **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 UASure<sup>®</sup> System using venous heparinized whole blood. The whole blood will be spiked to provide samples at four different glucose concentrations (5.4 to 18.4 mg/dL). Multiple replicates (n=20) were tested using multiple UASure<sup>®</sup> Meter and one lot of UASure<sup>®</sup> 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):	5.4	10.5	14.7	18.4
S.D. (mg/dL):	0.1	0.3	0.4	0.7
C.V%:	2.5	3.1	2.6	3.6

## Chapter 10. Specifications

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Test Strips:	UASure® Blood Uric Acid Test Strips
Test Range:	3 - 20 mg/dL (179 - 1190 $\mu$ mol/L)
Blood Source:	Capillary whole blood
Hematocrit Range:	35-50%
Display Type:	Large LCD screen
Memory:	10 blood uric acid 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 :**

IEC 61010-1    IEC 60601-1

EN 60601-1    EN 61010-1

EN 60601-1-2   EN 61326

## Chapter 11. Supplies

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Part Number	Product Name
U3000	UASure® Blood Uric Acid Monitoring System (EZ LET II Lancet)
U3004	UASure® Blood Uric Acid Monitoring System (Lancing Device)
U3500	UASure® Blood Uric Acid Control Solution
U3600	UASure® Blood Uric Acid Test Strips 25's (Bottle)
U3601	UASure® Blood Uric Acid Test Strips 25's (Aluminum foil package)
65235010001	Lancing Device
65295710804	Lancets 50's



## Chapter 12. 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



Do not re-use

## Chapter 13. Product Warranty

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The UASure® Blood Uric Acid 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.

