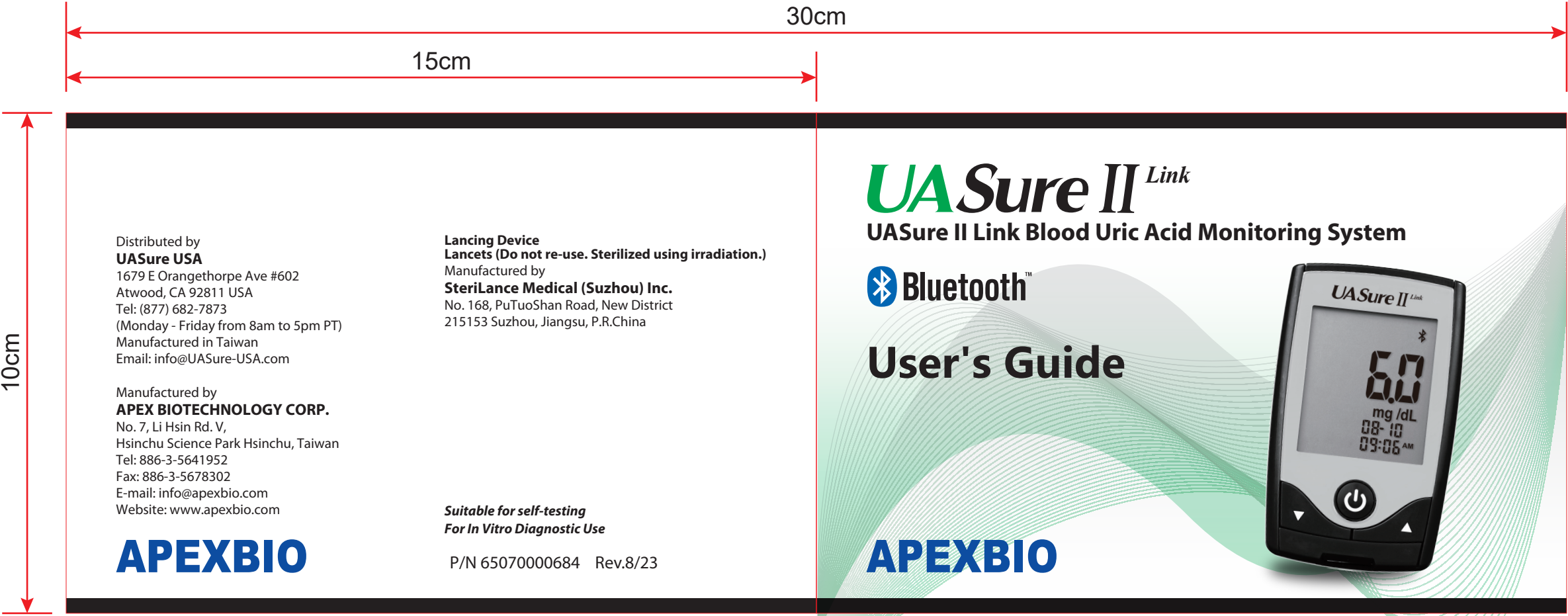


(FDA)
UASure II Link Manual Cover
SIZE: W15 x H10 cm
P/N 65070000684
Rev.8/23



UASure II^{Link}

UASure II Link Blood Uric Acid Monitoring System



User's Guide

APEXBIO



Distributed by

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APEXBIO

Lancing Device

Lancets (Do not re-use. Sterilized using irradiation.)

Manufactured by

SteriLance Medical (Suzhou) Inc.

No. 168, PuTuoShan Road, New District

215153 Suzhou, Jiangsu, P.R.China

Suitable for self-testing

For In Vitro Diagnostic Use

P/N 65070000684 Rev.8/23

Dear UASure II Link Owner

Thank you for choosing the UASure II Link Blood Uric Acid Monitoring System to help you easily monitoring your blood uric acid level. All of the information you need to use and maintain your new UASure II Link Blood Uric Acid Monitoring System is included in this manual and does not require any special training. Please read it carefully before use.

Your UASure II Link 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 for self-testing. The UASure II Link Blood Uric Acid Monitoring System displays plasma referenced results, which is comparable to the laboratory testing results.

For questions and inquiries, please contact the authorized representative.

Intended Use

The UASure II Link Blood Uric Acid Monitoring System is intended for quantitative measurement of uric acid level in fresh capillary whole blood drawn from fingertips. Testing is done outside the body (in vitro diagnostic use). It is indicated for self-testing by individuals at home, as an aid in monitoring blood uric acid level. The UASure II Link Blood Uric Acid Monitoring System is not intended to diagnose Hyperuricemia or Gout, and results obtained from using the UASure II Link Blood Uric Acid Monitoring System should not be used as a basis to alter medication without first consult a physician or healthcare professional.

IMPORTANT:

- Dehydration – Severe dehydration may lead to inaccurate blood uric acid. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- Hematocrit range –A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate blood uric acid test results.
- Not intended for use on neonates.
- Suitable for self-testing.

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Understanding Your UASure II Link Blood Uric Acid Monitoring System

Each UASure II Link system may include the following items:



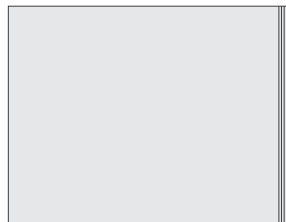
UASure II Link
meter



Lancets

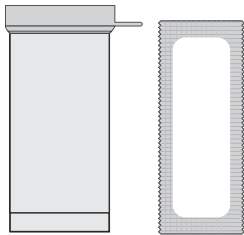


Lancing Device



User Guide

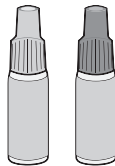
Test strip/ code card/ control solutions



The Uric Acid Test Strip
(vial or foil-wrapped)



Uric Acid Code Card



Uric Acid Control Solution
(Level 1, Level 2)

NOTE:

- Contents may change without notice.
- Lancets and Lancing Device are optional components.
- UASure II Blood Uric Acid Test Strips and UASure II Blood Uric Acid Control Solutions are optional and sold separately. Please contact the authorized representative for purchasing information.

The UASure II Link Blood Uric Acid Meter



Meter Display

Shows your test results, memory values, average, and other messages.

Enter (⏻) and ▲ ▼ buttons

Press (⏻) and hold to turn ON/OFF the meter, entering the Memory Mode or the Setup Menu.

Press ▲ or ▼ to enter control mode with test strip inserted, during meter setup, or to navigate the stored test values and averages.

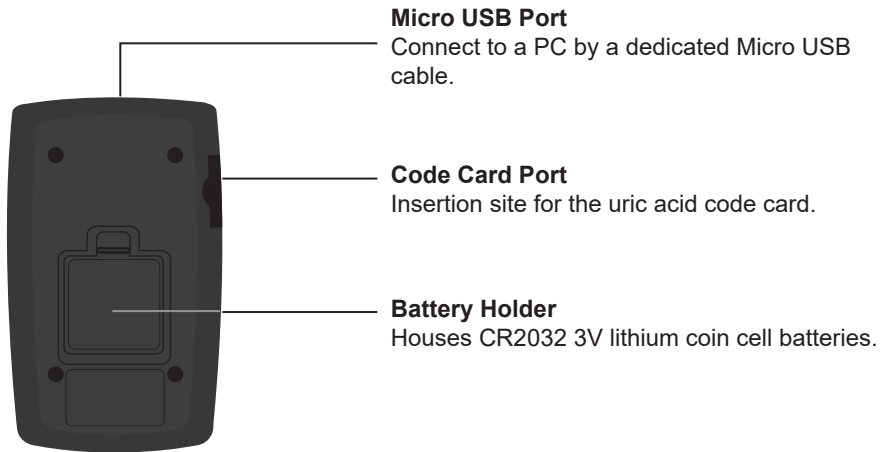
Test Strip Port

This is where you insert the test strip and the meter will turn on automatically.

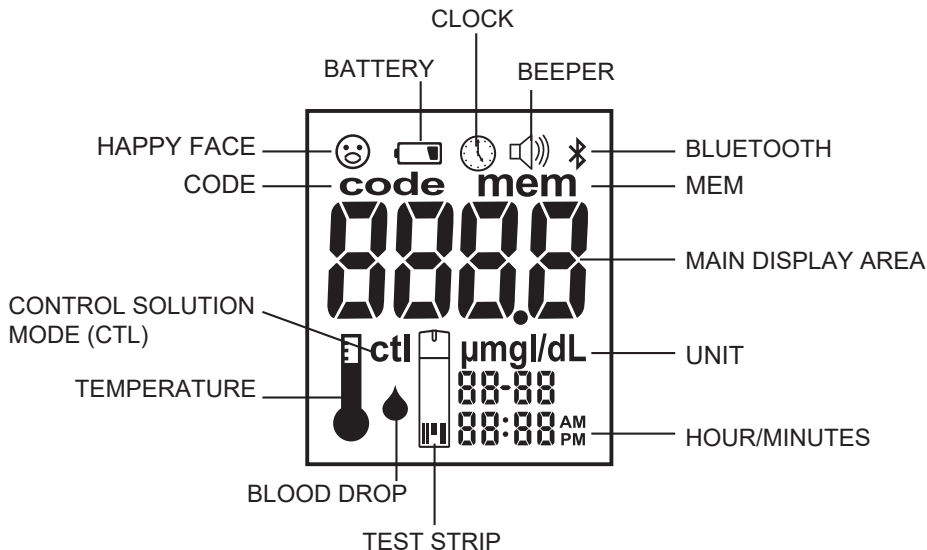
NOTE:

- The meter display is covered with a protective film. You can choose to remove the protective film or leave it. This does not affect the operation or performance of the meter.





The UASure II Link Blood Uric Acid Meter Display Screen



HAPPY Face	Indicates whether the meter electronic circuit works properly
BATTERY	Appears when the battery is low and needs to be replaced (see page 12)
CLOCK	Appears when setting date and time of the meter (see page 15)
BEEPER.....	Indicates the beeper is on (see page 18)
BLUETOOTH	Indicate Bluetooth is turn on
MEM	Indicates the number in the display area is a stored test value (see page 42)
MAIN DISPLAY AREA.....	Displays code number, test results, stored test results, result averages, and messages
UNIT	Unit of measurement for your blood uric acid
TEST STRIP	This icon will flash to prompt you to insert a test strip for testing
CTL	Indicates a control solution test (see page 22)
BLOOD DROP	This icon will flash to indicate the meter is ready for testing
CODE	Indicates current uric acid code number
TEMPERATURE	Appears when it is either too hot or too cold to test (outside the range 10°C~38°C (50°F~100°F)).

The UASure II Blood Uric Acid Test Strips

Contact Points

Insert this end to the test strip port on the meter



Sampling End

Apply blood or control solution here


The UASure II Blood Uric Acid Test Strips is uric acid specific, biosensor based test strip that can test uric acid in capillary whole blood in 10 seconds and requires about only 1.5 μL of blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assure that each reading you get is an accurate and meaningful result.

IMPORTANT:

- Be sure to use only the UASure II Blood Uric Acid Test Strip with the UASure II Link Blood Uric Acid Meter. Other brands of test strips will not work with the meter.
- The UASure II Blood Uric Acid Test Strip is sensitive to moisture and light. DO NOT leave any test strips outside the bottle or foil while not in use.
- Carefully discard used test strips and lancets in proper waste containers.
- DO NOT reuse test strip. Test strip is for single use only.

Setting Up Your New System

Inserting (or Changing) the Battery

The batteries need to be inserted before using your UASure II Link Blood Uric Acid Monitoring Meter for the first time or when the “” icon appears on the meter display screen.

Material you will need:

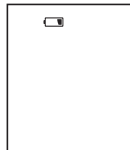
- One CR 2032 3V Lithium coin cell battery
- Your UASure II Link Blood Uric Acid Monitoring Meter

Step 1.


Turn meter off. Remove the battery cover on the back of the meter by pushing the tab and pulling the door up. Remove the old batteries.

Step 2.

Insert the new batteries according to the direction which is shown inside the battery compartment. Put the battery door back in the place and snap it closed.



NOTE:

- After replacing the battery, the meter will automatically prompt you to check the time and date of the meter when using a test strip to turn on the meter. If setting is correct, press “” again to exit, or if the time and date are not correct, turn to page 15 for Setting the Clock .
- Dates and stored results will not be erased when the batteries are replaced.
- Keep the meter out of the reach of children. Coin batteries may represent a choking hazard.
- The meter uses One CR 2032 3V Lithium coin cell battery. This type of battery can be found in many stores. Keep spare batteries at any time.
- Discard used batteries according to your local regulations.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period.

Meter Setup

Step 1.

Make sure the meter is OFF. To turn OFF the meter, press “⏻” and hold until the screen switches OFF.

Step 2.

Press “⏻” and hold until SET appears to enter the setup menu.



Step 3.

Press ▲ or ▼ to scroll through the setting menus (clock or beeper) and press “⏻” to enter each single menu.

NOTE:

At any time during setup, you may either press “⏻” to exit, or insert a test strip to perform a test. The changes made so far will be memorized by the meter.

Setting the Clock

Material you will need:

- Your UASure II Link Blood Uric Acid Meter

Begin Set Up

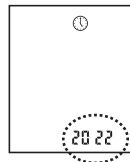
Step 1.

Press and hold “⏻” for 4 seconds to enter the setup menu.



Step 2.

Press ▲ or ▼ until meter display screen shows “⌚”. Press “⏻” to enter clock setting.



Set Year

Step 3.

The current year will flash. Use ▲ or ▼ to select the correct year.

Press “⏻” to confirm your choice and advance to set the month.

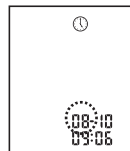
IMPORTANT:

- In order for the meter to determine a proper strip expiration date, the year/month/day of the meter must be setup properly before any test being performed.

Set Month

Step 4.

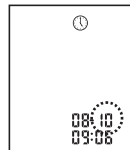
The current month will flash. Use ▲ or ▼ to select the correct month. Press “⏻” to confirm your choice and advance to set the day.



Set Day

Step 5.

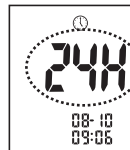
The current day will flash. Use ▲ or ▼ to select the correct day. Press “⏻” to confirm your choice and advance to set the 12-hour or 24- hour time format.



Set 12-hour or 24-hour Time Format

Step 6.

The time format will flash. Use ▲ or ▼ to select the time format of your choice. Press “⏻” to confirm your choice and advance to set the hour.



Set Hour

Step 7.

The current hour will flash. Use ▲ or ▼ to select the correct hour. Press “⏻” to confirm your choice and advance to set the minutes.



Set Minutes

Step 8.

The current minute will flash. Use ▲ or ▼ to select the correct minute. Press “⏻” to confirm your choice and return to the setting menus.



NOTE:

- Anytime during setup, you may insert a test strip to begin testing. The changes you have done so far will be memorized by the meter.
- If the date and time on your UASure II LINK Meter are not set, the test results and control results will not be stored in the meter memory.
- You may need to reset the date and time after replacing the batteries.

After setting your clock, you can continue to set your meter, press and hold “⏻” to turn off the meter, or insert a test strip to begin testing.

Beeper setup

Step 1.

Press and hold “⏻” for 4 seconds to enter the setup menu.



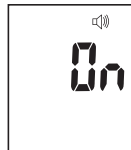
Step 2.

Press ▲ or ▼ until meter display screen shows “🔊”. Press “⏻” to enter beeper setting.



Step 3.

Use ▲ or ▼ to turn on/off the tone sound. Press “⏻” to confirm and return to the setting menus.



NOTE:

- Anytime during setup, you may insert a test strip to begin testing. The changes you have done so far will be memorized by the meter.

After setting your beeper, you can continue to set your meter, press and hold “⏻” to turn off the meter, or insert a test strip to begin testing.

Coding the Meter

You must code the meter before you begin uric acid testing on your UASure II Link Blood Uric Acid Meter. Coding is a process of programming the meter to the new of uric acid test strips and to ensure accurate test results. A new code card is packaged along with each box of UASure II Blood Uric Acid Test Strips.

Materials your will need:

- A UASure II Blood Uric Acid Test Strip with its code card
- Your UASure II LINK Meter

NOTE:

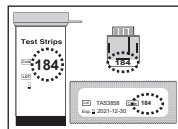
- Make sure the Test Strip is not expired. Check the test strip expiration date on the box and the test strip bottle or the aluminum foil packaging.
- Make sure the code card is securely lodged into the code card port on the top of the meter.

Step 1.

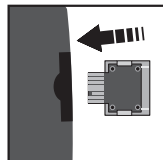
Locate the code card () in the package of UASure II Blood Uric Acid Test Strip.

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 into the code card port located on the top of the meter. Make sure the code card is completely inserted with code number facing down.

**IMPORTANT:**

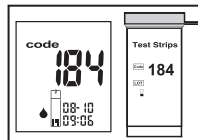
- The code card found in the UASure II Test Strip package is for use with the particular package only. Different packages of UASure II Test Strip and other brands of test strips will produce inaccurate results.
- Re-coding needs to be done when a new package of test strip is opened for use.
- Code number will be memorized by the meter even if the code card is removed.

Step 4.

Insert a UASure II Blood Uric Acid Test Strip with the blood sample reaction zone facing up to turn ON the meter automatically. Make sure the test strip contact point is fully inserted into the meter. Close the test strip vial immediately after you've taken out a test strip.

Step 5.-Confirming the code number

The meter will run a series of self testing. A 3-digit code number will be displayed on the meter display screen. Verify the code number on the screen with that on the code card and the test strip package. All three sets of numbers should be the same. After coding the meter, insert a test strip to begin testing.



NOTE:

- If the code number displayed on the screen does not match the code number printed on the test strip bottle or on the package, the test results will be inaccurate.
- If error messages (Er 6) appear, see Solving Problems on page 47.

Control Solution Testing (Optional)

Performing a Uric Acid Control Solution Test

The purpose of the uric acid control solution testing is to validate the performance of the UASure II Link Blood Uric Acid Monitoring System using the testing solution with a known range of uric acid. UASure II Blood Uric Acid Control Solution is optional and sold separately.

Please contact our authorized representative near you for purchase information.

A test with control solution can be done when:

- Using the meter for the first time
- You open a new bottle of UASure II Blood Uric Acid Test Strips
- You leave the cap of the test strip vial open for a while
- You drop the meter
- You suspect your UASure II Link Blood Uric Acid Meter and UASure II Blood Uric Acid Test Strips are not working properly
- You want to practice the testing procedure

Materials you will need:

- UASure II Uric Acid Control Solution(Level 1 and Level 2)
- Your UASure II Link Blood Uric Acid Meter
- A new UASure II Blood Uric Acid Test Strips
- A uric acid code card

IMPORTANT:

- Use only UASure II Uric Acid Control Solution(Level 1 and Level 2) with the UASure II Blood Uric Acid Test Strips. Other brands of control solution will produce inaccurate results.
- 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.
- The control solution should be stored at 2°C~8°C (36°F~46°F) in the refrigerator. DO NOT FREEZE. When the control solution needs to be used again, allow it to stand under room temperature at least 30 minutes before use.

Step 1.

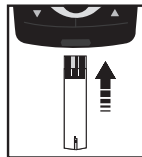
You must code the meter before performing a uric acid control solution test, see Coding the Meter on page 19.

IMPORTANT:

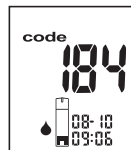
- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip).
- Use each test strip immediately after removing it from its package.
- After removing a test strip from the bottle, replace the bottle cap immediately and close it tightly.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- When first opened, record the "open date" on the test strip bottle label. Three months after the first opening, discard the bottle and the remaining test strips.
- Ensure that testing is performed in an environment between 10°C~38°C(50°F~100°F) and 20%~85%RH, and allow 10 to 15 minutes for it to reach the new temperature before use.
- If the meter displays a temperature icon "⚠", that means the meter has been exposed to temperature that is outside of its normal operating range. Move the meter into an environment which is between 10°C~38°C (50°F~100°F) , and allow 10 to 15 minutes to reach the operating temperature. Meter will not start testing if it is used outside the operating temperature range.

Step 2.

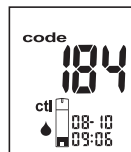
Insert a UASure II Blood Uric Acid Test Strip with the blood sample reaction zone facing up to turn ON the meter automatically. Make sure the test strip contact point is fully inserted into the meter. Close the test strip vial immediately after you've taken out a test strip.

**Step 3.**

The meter will run a series of self testing, and the current code number will be displayed with flashing blood drop and test strip icons appear on the meter display screen. Verify the displayed code number with the code number printed on the code card and the test strip package.

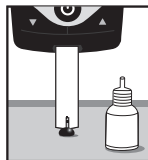
**Step 4.**

Press ▲ or ▼ to enter the control mode. You will see "ctl" displayed on the meter display screen.



Step 5.

Squeeze a drop of uric acid control solution (Level 1 or Level 2) onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.

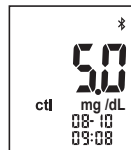


Step 6.

Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip.

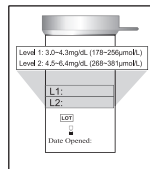
Step 7.

The screen will begin to count down. After 10 seconds, the control solution testing result will appear on the meter display screen. A “ctl” flag will also be attached when results are shown on the screen.



Step 8.

Compare the reading on the screen to the control range printed on the test strip bottle or its package. If the reading does not fall within the control range printed on the test strip bottle or its package, see Control Solution Test Trouble Shooting on page 42.



Step 9.-uploading data

When the meter is paired with a portable device the test results are uploaded to the device. The test results are uploaded to the device and the Bluetooth symbol flashes. After the transfer is complete, the Bluetooth symbol disappears.



NOTE:

- Control solution testing results will be stored into the meter's memory and indicated by "ctl" icon.
- Replace the bottle cap on the control solution bottle immediately after use.
- If error messages (Er 2, etc.) appear, see Solving Problems on page 47.
- When the Bluetooth function is turned on again, untransmitted data is transferred to the portable device.
- If the BLE status is normal, the BLE icon will flash quickly.
- When BLE data transmission is started, the BLE icon flashes slowly.

Step 10.

The meter will automatically turn off by pressing the eject switch or by pulling the test strip out by hand. Throw the used strip into the appropriate waste basket. The meter will also automatically turn off after 1 minute of inactivity.

IMPORTANT:

- Do not reuse test strips .

Perform other levels of control solution testing by repeating the above steps.

Control Solution Test Trouble Shooting

If your control solution testing is out of range (too high or too low), it may be caused by the following:

Possible Causes	What you can do ...
Wrong brand of control solution being used	Make sure you are using UASure II Uric Acid Control Solution(Level 1 & 2) for uric acid test.
Control solution not at right operation temperature	Make sure the testing environment is between 10°C~38°C (50°F~100°F) for uric acid test.
Control solution not at right storage temperature	Make sure the storage environment is between 2°C~8°C (36°F~46°F) for uric acid control solution.
Improper coding of the meter	Make sure the code number displayed on the meter matches the code number of the test strip package.

Possible Causes	What you can do ...
Expired or contaminated control solution or damaged test strips	Check the expiration and opened date on bottles of both control solution and test strips. Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.
Test strip deterioration	Repeat the test with a new test strip.
Meter malfunction	Please contact the authorized representative for questions and inquiries.

Testing Your Blood Uric Acid

Materials you will need:

- Your UASure II Link Blood Uric Acid Monitoring Meter
- A new UASure II Blood Uric Acid Test Strips
- A uric acid code card
- Lancing device with a sterile, unused lancet

Before you begin, make sure:

- Set up your meter properly and run a control test if necessary. See Setting Up Your New System on page 12 and Control Solution Testing on page 22 for more details .
- Wash your hands and testing site thoroughly with soap and warm water, and dry well.
- You are testing in an area between 10°C~38°C (50°F~100°F) and 20%~85% RH. Your meter will not test outside of this range and will display "!" on the screen. Move the meter into an area that is between 10°C~38°C (50°F~100°F), and let it sit for 10 to 15 minutes before testing again.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

Preparing Your Lancing Device

CAUTION:

- The lancets are for single use only.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Discard used lancet according to your local regulations. Used lancets are biohazard materials and can transmit blood-borne diseases. Dispose them according to local government regulations to avoid injury or contamination.
- When performing a blood uric acid test, use a new sterile lancet every time. If alcoholic wipes are used to cleanse the puncture sites, make sure the area is dry before the blood sample is obtained.

Step 1.

Wash puncture sites with soap and warm water and dry thoroughly. Warm water stimulates blood flow and makes it easier to obtain a sample.

Step 2.

Hang the arm down at the side for 10 to 15 seconds massaging through the wrist, palm, and then finger. This can stimulate the blood flow more quickly.

Step 3.

Hold the lancing device (puncture) or lancet against the puncture site and lance it. Follow manufacturer's instruction for how the lancing device (puncture) or lancet should be used.

TIP:

- To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

Performing a Blood Uric Acid Test

Step 1.

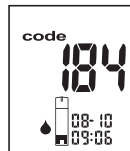
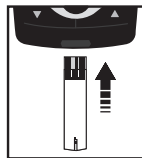
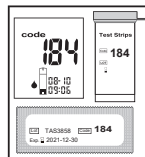
You must code the meter before performing a blood uric acid test, see Coding the Meter on page 19.

Step 2.

Insert a UASure II Blood Uric Acid Test Strip with the blood sample reaction zone facing up to turn ON the meter automatically. Make sure the test strip contact point is fully inserted into the meter. Close the test strip vial immediately after you've taken out a test strip.

Step 3.

The meter will run a series of self testing, and the current code number will be displayed with flashing blood drop and test strip icon appear on the meter display screen. Verify the displayed code number with the code number printed on the code card and the test strip package.



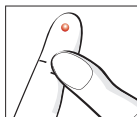
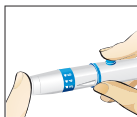
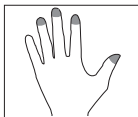
IMPORTANT:

- Check the expiration date printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle.

- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- For vial test strip, record the “date opened” on the bottle label. Discard the bottle and any remaining test strips three months after the date of opening.
- Insufficient blood specimen may cause incorrect results.
- If error messages (Er 2, etc.) appear, see Solving Problems on page 47.

Step 4.

Hold the lancing device (use the blue cap) against the side of your fingertip and press the release button to create a puncture.

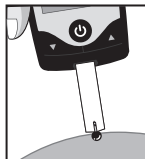


TIP:

- Gently massage your hand and finger toward the puncture site to form a drop of blood (approximately:●). Do not “milk” or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

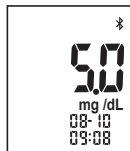
Step 5.

Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.



Step 6.

The screen will start to count down. After 10 seconds, the uric acid testing result will appear on the meter display screen.



CAUTION:

- If you see “HI” or “LO” is displayed, your blood uric acid level may be beyond the meter measurement range (above 20 mg/dL or below 3 mg/dL). Test again using fingertip testing. If you still receive the same result, call your physician or healthcare professional immediately.
- If you get result of “HI” or “LO”, it will be stored automatically in memory as 20 mg/dL or 3 mg/dL.

Step 7. -uploading data

Bluetooth is always on. When the meter is paired with a portable device and the app is open, the test results are uploaded to the device. The test results are uploaded to the device and the Bluetooth symbol flashes. After the transfer is complete, the Bluetooth symbol disappears.



IMPORTANT:

- If error messages (Er5, Er7, etc.) appear, see Solving Problems on page 47.
- If the BLE status is normal, the BLE icon will flash quickly.
- When BLE data transmission is started, the BLE icon flashes slowly.

Step 8.

The meter will automatically turn off by pulling the test strip out by hand. Throw the used strip into the appropriate waste basket. The meter will also automatically turn off after 1 minute of inactivity.

Step 9.

Remove the used lancet from your lancing device according to instructions and discard it into a proper wastebasket.

IMPORTANT:

- Used lancets and strips are biohazard materials and can transmit blood-borne diseases. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets and strips.
- When the Bluetooth function is turned on again, untransmitted data is transferred to the portable device.
- DO NOT link unknown person's BLE-equipped devices with your UASure II Link meter.

Understanding Your Test Results

Understanding Your Blood Uric Acid Test Results

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
- Medication

Uric acid testing should be performed on fasting. If you feel your test results do not reflect how you feel, repeat the test. If the test result is still the same, contact your healthcare professional.

Uric acid is the end product of purine (part of DNA) metabolism. The body produces purine during tissue remodeling and breakdown. About 20% of uric acid is derived from purines ingested in food. Caused of hyperuricemia can be divided into two major categories: decreased clearance of uric acid from the kidney and increased synthesis of uric acid.

All patients should be encouraged to modify their lifestyle including limiting alcohol intake, encouraging weight loss where appropriate and decreasing food rich in purines.

Food High in Purines

Very high:

Hearts, herring, mussels, yeast, smelt, sardines, sweetbreads

Moderately high:

Anchovies, grouse, mutton, veal, bacon, liver, salmon, turkey, kidneys, partridge, trout, goose, haddock, pheasant, scallops

Normal Blood Uric Acid Readings

Target blood uric acid levels are as follows:

Male: 4.0~8.5 mg/dL

Female: 2.7~7.3 mg/dL

High Blood Uric Acid Readings

Men with test result higher than 8.5 mg/dL, or women with a test result higher than 7.2 mg/dL, may have a medical condition known as "hyperuricemia". Hyperuricemia patients are at risk of renal disease, and some patients may develop into "gout," a condition characterized by swelling in the joints and may hurt severely from time to time.

Low Blood Uric Acid Readings

No significant symptoms or diseases are found related to low blood uric acid. Contact your physician for more information if you get low uric acid reading.

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.

IMPORTANT:

- A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate blood uric acid test results.

Reference:

Pagana KD, Pagana TJ, Pagana TN. Mosby's Diagnostic and Laboratory Test Reference. Maryland Heights, MO: Mosby; 2019.

Viewing Stored Readings from Memory


Uric Acid Test Results from Memory

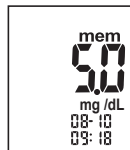
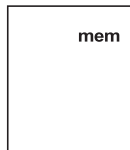
Your UASure II Link Blood Uric Acid Meter can store up to 200 uric acid test and control results with date and time. You will need to set your meter's date and time before using the memory, see Setting Up Your New System on page 15. The meter will not memorize any test or control results if the date and time are not set.

Material you will need:

- Your UASure II Link Blood Uric Acid Meter

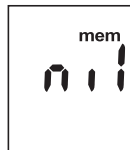
Step 1.

Press and hold “” and hold until mem appears to enter the memory mode.



Step 2.

The most recent test result will appear on screen. Press ▲ to view your result from the most recent to the oldest. Press and hold either ▲ or ▼ will accelerate scrolling. When scrolling to the end of results in the memory, the meter display screen will show “nil”.

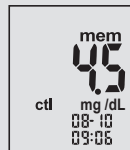



Step 4.

Press and hold “” to switch the meter off or OFF.


NOTE:

- Control testing results will be flagged by a “ctl” icon when viewing stored readings.
- When the memory is full, perform a new test will delete the oldest test result.
- If you get result of “HI” or “LO”, it will be stored automatically in memory as 20 mg/dL or 3 mg/dL.



After you finish viewing memory, press and hold “” to turn off the meter, or insert a test strip to begin testing.

NOTE:

- Anytime during viewing memory, you may either press “” to exit, or insert a test strip to begin testing.

Upload Data

Test results stored in the UASure II Link Blood Uric Acid Meter's memory can be transmitted to your personal computer or mobile devices.

Material you will need:

- Your UASure II Link Blood Uric Acid Meter
- A dedicated micro USB cable

Step 1.

Insert a dedicated Micro USB cable into the data port to transmit stored readings.

Step 2.

After you finish uploading data, remove the cable to turn off the meter.



NOTE:

The USB cable should be connected to a device complies with IEC 60950-1 or IEC 62368-1 standard.

Caring for the Meter

Caring your UASure II Link Blood Uric Acid Meter is easy. Follow these simple guidelines to keep your UASure II Link Blood Uric Acid Meter working properly.

Cleaning the Meter

- If the meter gets dirty, wipe the surface of the meter using a moist (NOT WET) lint-free cloth dampened with a mild detergent.
- Do not get water inside the UASure II Blood Uric Acid Meter. Never immerse the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.
- Do not contaminate the strip holder with blood or control solution.

Disinfecting the Meter



- Please clean the meter before disinfection
- Disinfect the surface of the meter with recommended solutions (soapy water, 10% bleach, and 75% alcohol)
- Wipe the meter with a soft damp cloth.
- Do not spray the solution on the meter, or immerse the meter in any liquid.
- Do not try to clean the test strip holder.
- Please note that 75% alcohol is not effective against viral.




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 environment between 10°C~38°C(50°F~100°F) and 20%~85% RH.
- 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.
- Always close bottle cap immediately after removing a test strip and make sure it is closed tightly.
- Do not take the meter apart. Doing so will void the warranty.
- Do not use this meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
- Do not use this meter near cellular or cordless telephones, walkie-talkies, garage door openers, radio transmitters, or other electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
- Dispose of the meter according to your local regulations for correct disposal.



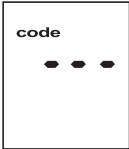
Solving Problems

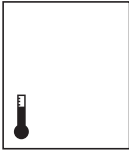


This section details the significant display screen messages and error codes you may encounter when using your UASure II Link Blood Uric Acid Monitoring Meter with UASure II Blood Uric Acid Test Strips.

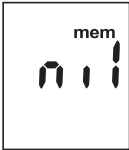
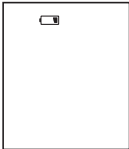
Message	What It Means	What You Should Do
	Meter failure	<ul style="list-style-type: none">• Replace the batteries and turn on the meter again.• If problem persists, contact our authorized representative.
	<ul style="list-style-type: none">• The strip has been used or contaminated• Blood applied too early	<ul style="list-style-type: none">• Please insert an unused test strip to start a new test.• Wait for the blood droplet icon flashes on the screen and apply your blood.

Message	What It Means	What You Should Do
	Not enough sample on the test strip to start	<ul style="list-style-type: none"> Repeat the test with a new test strip. Testing Your Blood Uric Acid on page 31.
	Test strip removed during countdown	<ul style="list-style-type: none"> Turn off the meter and repeat the test with a new test strip.
	Bluetooth Module Invalid	<ul style="list-style-type: none"> Er5 just a warning, and then continue to the next step. Measurements are done without the Bluetooth function. If problem persists, contact our authorized representative.

Message	What It Means	What You Should Do
	Code card shows the date is out of range	<ul style="list-style-type: none"> • Make sure the clock is set correctly. To reset the date & time, please remove the battery from the meter for at least 1 minute. Reinsert the battery, press  and hold or insert an unused test strip to turn ON the meter, and set the clock starting with the year. • Please make sure the code card is the correct one which came with the test strips package. • Check the test strip expiration date on the vial label or foil packet. Make sure the test strips are within their expiration date.
	Meter authorization fails during BLE bounding procedure	<ul style="list-style-type: none"> • Check Bluetooth device is working well and repeat confirm to pairing • If problem persists, contact our authorized representative.

Message	What It Means	What You Should Do
	Data transmission is interrupted by inserting the test strip	<ul style="list-style-type: none"> When the Bluetooth function is turned on again, untransmitted data is transferred to the portable device.
	Data transmission is interrupted by the portable device	<ul style="list-style-type: none"> When the Bluetooth function is turned on again, untransmitted data is transferred to the portable device.
	<ul style="list-style-type: none"> Not coded with a code card Code Card type error 	<ul style="list-style-type: none"> Confirm that the code card is inserted into the meter before inserting the test strip. Code your meter with a code card, see Coding the Meter on page 19.

Message	What It Means	What You Should Do
	Temperature out of range	<ul style="list-style-type: none"> Move the meter into an area that is between 10°C~38°C (50°F~100°F) and 20~85% RH for uric acid test, and allow 10 to 15 minutes for it to reach the new temperature
	Uric Acid test result higher than 20 mg/dL	<ul style="list-style-type: none"> Wash and dry your hands and repeat the test using a new test strip. If the result is still “HI”, contact your physician or healthcare professional immediately.
	Uric Acid test result lower than 3 mg/dL	<ul style="list-style-type: none"> Wash and dry your hands and repeat the test using a new test strip. If the result is still “LO”, contact your physician or healthcare professional immediately.

Message	What It Means	What You Should Do
	No memorized uric acid test results in the meter	<ul style="list-style-type: none"> • Check if the date and time on your meter is set up. See Setting Up Your New System on page 12. • Start testing your blood uric acid, see Testing Your Blood Uric Acid on page 31. • For a blood test, insert an unused test strip to turn ON the meter automatically.
	Dead battery	<ul style="list-style-type: none"> • Change the batteries according to instructions for Inserting (or Changing) the Battery on page 12.

Product Warranty

UASure USA warrants the UASure II Link Blood Uric Acid Monitoring Meter 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 Corporation is limited to repair or replacement and in no event shall UASure USA 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 UASure USA authorized dealer responsible for the sale of the system.

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

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Specifications

Product:	UASure II Link Blood Uric Acid Monitoring System
Tested items:	Blood uric acid level;
Test strip coding:	Coding required
Sample	Fresh capillary whole blood from fingertips
Test range:	3~20 mg/dL
Hematocrit Range:	20~60 %
Sample size:	Minimum 1.5 µL
Test time:	10 seconds
Batteries:	1x 3V CR2032 batteries
Battery life:	1000 tests of continuous use
Memory:	200 results with date and time
Data transfer:	Via dedicated micro USB cable or a Bluetooth device
Dimensions:	L80 x W50 x H14 (mm)
Weight:	32g
Operating conditions:	10~38°C (50~100°F) and 20%~85% RH.
Storage/transport conditions:	Meter at -20°C~50°C (-4°F~122°F) Test strips at 4°C~30°C (39°F~86°F)

Automatic turn off:

- After 90 seconds of inactivity before the test (sensor strip inserted into the meter, drop icon flashing)
- After 60 seconds of inactivity after testing and setup

Electromagnetic Compatibility:

The UASure II Link meter complies with the electromagnetic requirements specified in IEC 60601-1-2 Edition 4.0 including selected electrostatic discharge immunity testing based on the basic standard IEC 61000-4-2. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the UASure II Link meter.

For additional information, refer to UASure II Blood Uric Acid Test Strips insert

Wireless Technology : Bluetooth 5, with the operating characteristics as following:

- Radio Frequency Band: 2.4 GHz–2.483 GHz
- Maximum Radio Transmitter Power: 4 dBm
- Security Encryption: 128-bit AES (Advanced Encryption Standard) CCM, ECB, AAR
- The transmitted distance between the meter and the mobile device : within a range of 10 meters.

Quality of service for the wireless connectivity for safe and effective data downloading:

- Acceptable latency: 4 seconds
- Max throughput: low speed; 21 kbps
- Acceptable level of probability for loss of information within the network: probability is 0%
- Accessibility/ signal priorities of the network: only Bluetooth is available
- Data integrity: check sum function for transmitting and receiving packets.

Supplies

S95048	UASure II Link Blood Uric Acid Monitoring System (Complete Kit)
S95049	UASure II Link Blood Uric Acid Monitoring System (Basic Kit)
S5640993	UASure II Blood Uric Acid Test Strip (25s, Vial)
S5640994	UASure II Blood Uric Acid Test Strip (50s, Vial)
S5640995	UASure II Blood Uric Acid Test Strip (5s, Foil Packets)
S5640996	UASure II Blood Uric Acid Test Strip (10s, Foil Packets)
S5640997	UASure II Blood Uric Acid Test Strip (25s, Foil Packets)
S5640998	UASure II Blood Uric Acid Test Strip (50s, Foil Packets)
S5800397	UASure II Uric Acid Control Solution (L1)
S5800398	UASure II Uric Acid Control Solution (L2)
S5800399	UASure II Uric Acid Control Solution (L1+L2)

UASure II Link Blood Uric Acid Contents

Confirm that the system contains the following items:

Product	Ref.	Meter	Lancing Device	Lancet	Strip	Control Solution
Complete Kit	S95048	V	V	V	V	
Basic Kit	S95049	V	V			

Federal Communications Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio / TV technician for help.

CAUTION:

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

RF exposure warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

