Renal Function Analysis Meter (RFM-101) User's Manual

Renal Function Analysis Meter

Identification

Meter: RFM-101

Test strips: RFS-101,CRS-101,UAS-101,URS-101

Important Safety Instructions

- Misuse of electrical meter can cause electrocution, burns, fire and other hazards.
- Do not place the meter in liquid, nor put it where it could fall into liquid. If the meter becomes wet, unplug it before touching it.
- Use the meter only for the purpose described in the instructions for use.
- Failure to use the meter in the manner specified by the manufacturer may damage the protection provided by the meter.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- Do not use the meter if it is not working properly or if it has suffered any damage.
- Do not let the meter come into contact with surfaces which are too hot to touch.
- Do not use the meter where aerosol sprays are being used or where oxygen is being administered.
- Do not use the meter out of doors.
- Control solution only purchased from local distributor or manufacturer
- Keep these instructions.
- For profesional use.

RFM-101 insert 20191125.indd 1 2019/11/27 10:41:57

Table of Contents

Renal Function Analysis Meter 1
Section 1 Introduction 3
Section 2 Getting Started 4
Section 3 Components 7
Section 4 Initial Setup 14
Section 5 Meter Setup and Options 15
Section 6 Testing 17
Section 7 Memory/Communication 25
Section 8 Optical Verify Strip Test 26
Section 9 Quality Control 27
Section 10 Maintenance 30
Section 11 Precautions 32
Section 12 Limitation 33
Section 13 Troubleshooting 34
Section 14 Meter Performance 35
Appendix 1 Meter Specifications 36
Appendix 2 Labelling And Information 37
Appendix 3 Warranty 38

RFM-101 insert 20191125.indd 2 2019/11/27 10:41:57

Section 1 Introduction

The Renal Function Analysis Meter is intended for the quantitative determination of Uric Acid (UA), Creatinine (CR) and Urea (UR) in capillary blood, venous whole blood, plasma and serum. The easy to operate system consists of a portable meter that analyzes the intensity and color of light reflected from the reagent area of a Test strip, ensuring quick and accurate results.
The Renal Function Analysis Meter provides results. The Renal Function Analysis Meter can store up to 500 results and records. The meter can be operated by charging battery.

To ensure accurate results:

- Read instructions carefully and complete any necessary training before use.
- Use the code chip that is included in each box of test strips.
- Only use the Renal Function test strips with the Renal Function Analysis Meter.
- For in vitro diagnostic use only. Renal Function Analysis Meter is only to be used outside the body for testing purposes.
- For professional use.
- Keep out of reach of children.

Principle of measurement

The analyzer applies the principle of photochemistry and is used with Renal Function test strips (RFS-101, UAS-101, CRS-101, URS-101) .The whole blood sample to be tested is added into the sample area of the strip. In the process of rapid infiltration, blood cells are filtered out or dissolved. The substrate reacts with enzymes and chemicals in the reaction layer and lead to the color change, then the color intensity is proportional to the concentration of the substance.

RFM-101 insert 20191125.indd 3 2019/11/27 10:41:58

Section 2 Getting Started

Please check the following requirements when you first receive our products: Unpacking, Checking delivery for completeness, Checking for damage during transport. If you have any question, please contact the manufacturer.

Before testing, read the instructions carefully and learn about all the components of the Renal Function Analysis Meter. Depending on the package type, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details on which components are included with your purchase. The following items are needed to perform a test:

Renal Function Analysis Meter

Test Strip
(RFS-101)

Test Strip
(UAS-101, CRS-101, URS-101)

Optical Verify Strip

Safety Lancet

Code Chip

Lancing Device

Capillary Transfer Tube/Dropper

Carrying Case

RFM-101 insert 20191125.indd 4 2019/11/27 10:41:58

Component Descriptions

01. **Renal Function Analysis Meter:** Reads the test strips and displays the concentrations of UA, CR, UR.
02. **Test Strips:** Part of the system, these are inserted into the meter to measure the concentrations of Uric Acid (UA), Creatinine (CR) and Urea (UR).
03. **Optical Verify Strip:** Verifies the proper operation of the meter by checking that the meter can detect a pre-calibrated value.
04. **Safety Lancets:** Used to draw blood specimens. Discard after use.
05. **Code Chip:** Automatically calibrates the meter with the code number when inserted into the meter.
06. **Lancing Device:** Used with sterile lancets to prick the fingertip for blood specimen collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.
07. **Sterile Lancets:** Used with the lancing device to draw blood specimens for individual test. Sterile lancets are inserted into the lancing device for each blood draw and discarded after use.
08. **Capillary Transfer Tubes/Droppers:** Collects capillary blood from fingertip blood testing for accurate results.
09. **Carrying Case:** Provides portability for testing.
10. **Instructions For Use:** Provides detailed instructions on using the Renal Function Analysis Meter.
11. **Test Strips Package Insert:** Provides detailed instructions on using the Renal Function test strips.
12. **Control Solution:** Verifies the proper operation of testing and validates the test strip and meter are working together properly.
13. **Control Solution Package Insert:** Provides detailed instructions on how to

RFM-101 insert 20191125.indd 5 2019/11/27 10:41:58

use the Control solution.

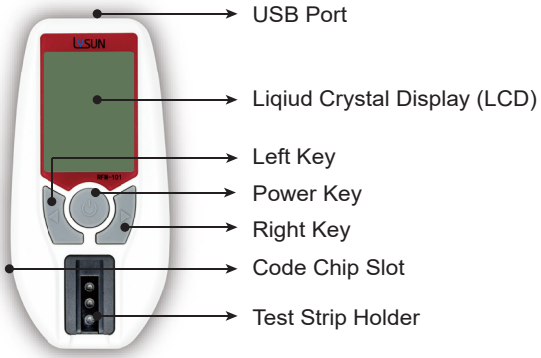
14. **Warranty Card:** Card included in the package, which should be completed and returned to the distributor to qualify for the 2-year meter warranty.

⚠ **Caution:Test strip, safety lancets, sterile lancets and capillary transfer tubes/droppers are disposable materials. Please use them before the expiration date.**

RFM-101 insert 20191125.indd 6 2019/11/27 10:41:58

Section 3 Components

The Renal Function Analysis Meter reads the test strips and displays the concentrations of Uric Acid (UA), Creatinine (CR) and Urea (UR). Use this diagram to become familiar with all the parts of the meter.



Meter Use and Precautions

- Do not get water or other liquids on or inside the meter.
- Keep the Test Strip Holder clean.
- Keep the meter dry and avoid exposing it to extreme temperatures and humidity.
- Do not drop the meter or get it wet. If the meter is dropped or has gotten wet, ensure the meter is working properly by running an Optical Check. Refer to optical verify strips for details.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to Maintenance for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

RFM-101 insert 20191125.indd 7 2019/11/27 10:41:58

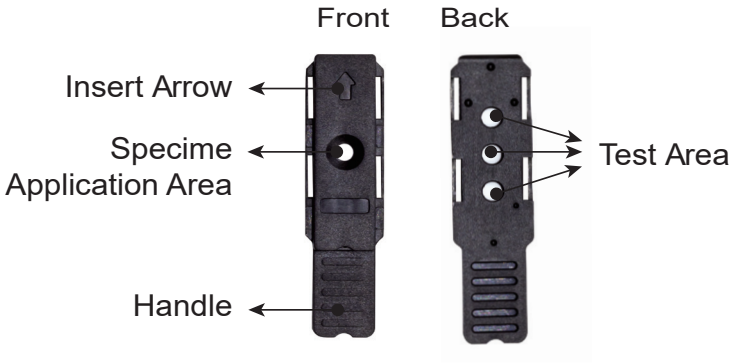
Note: Follow proper precautions and all local regulations when disposing of the meter.

Test strips

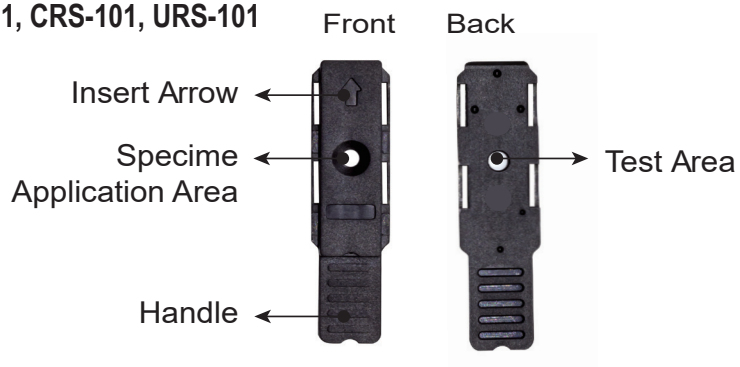
The Renal Function test strips are plastic devices that work with the Renal Function Analysis Meter to measure the UA, CR, UR concentration in whole blood, plasma and serum.

Test strip appears as shown below:

RFS-101



UAS-101, CRS-101, URS-101



RFM-101 insert 20191125.indd 8 2019/11/27 10:41:59

Test strips can detect Uric Acid (UA), Creatinine (CR) and Urea (UR).

Insert Arrow: Located on the front of the test strip, the arrows indicate the direction in which the test strip should be inserted into the meter.

Specimen Application Area: After the strip is inserted into the Test Strip Holder, apply the correct specimen volume to the region in the center of the test strip.

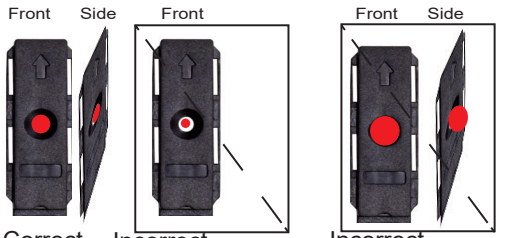
Handle: Located on the end of the test strip, the handle is used to insert and remove the test strip from the meter.

Test Area: Located on the back of the test strip. The meter will detect and read this area to give results of UA, CR and UR levels.

Specimen Application

For best results, fill the Specimen Application Area with the correct specimen volume. Incorrect results may occur if the specimen is not applied correctly or if the Specimen Application Area is not filled with the correct amount.

Before Testing



After applying the specimen, ensure that the Specimen Application Area is completely covered. The Specimen Application Area should remain covered throughout the entire test. If the Specimen Application Area is not covered or if there is too much specimen covering the Specimen Application Area, repeat the test with

RFM-101 insert 20191125.indd 9 2019/11/27 10:42:05

a new test strip.

Note: If the specimen applied to the Specimen Application Area is not enough, do not add more specimens to the test strip. Instead, retest with a new strip. If the E-2 Error or another error appears on the display, please discard the used strip and retest with a new strip.

Code Number

Printed on each package of test strips is a code number , lot number, unopened expiration date, and test quantity.

Test strip Precautions and Instructions for Use

- Test strips should be stored in their tightly capped protective canister or foil pouch to keep them in working condition.
- Do not store test strips outside of their package. Test strips must be stored in the original package and sealed tightly.
- Do not transfer test strips to a new package or any other container.
- Replace the cap on the test strip canister immediately after removing a test strip.
- A new canister of test strips may be used for 3 months after first being opened. The opened expiration date is 3 months after the date the canister was first opened. Write the opened expiration date on the canister label after opening. Discard the canister 3 months after it is first opened. Usage after this period may result in inaccurate readings.
- For in vitro diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in anyway.
- Do not reuse test strips.
- Before performing a test, make sure that the code number on the meter display matches the number shown on the test strip canister or foil pouch and on the

RFM-101 insert 20191125.indd 10 2019/11/27 10:42:05

ink-jet printing on the code chip.

- Refer to the test strip package insert for more details.

Optical verify strip

The Renal Function optical verify strips work with Renal Function Analysis Meter to ensure the optical part is working properly. After the optical verify strip is inserted into the meter, the meter's optical part detects the color intensity of the optical verify strip. The meter displays ***OH*** or ***FL*** to indicate whether the meter is functioning properly.

The optical verify strip appears as shown below:

Precautions

- Store in the closed canister at room temperature or in the refrigerator within 2-30°C. Avoid exposure to direct sunlight, extreme temperatures, and humidity.
- Optical verify strip should be stored in their tightly capped canister to keep them in working condition.
- Keep the optical verify strip clean. Do not touch the test area of the strip.
- Take the optical verify strip out of the canister. Put the optical verify strip back and close the canister tightly immediately after use. Do not use contaminated,

RFM-101 insert 20191125.indd 11 2019/11/27 10:42:05

discolored, or damaged optical verify strip.

- Do not use it after the expiration date.
- For in vitro diagnostic use only.

Storage and Handling

- Store optical verify strips in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store in its closed canister within 2-30°C with less than 90% humidity.
- Replace the cap on the strip canister immediately after removing a strip. Expired strip may produce incorrect test results.

Control Solution

The Renal Function Control Solution contains stabilizers, preservatives and added chemicals. To confirm that the test strip and meter are working together properly and that the test is being performed correctly, the control solution is applied to the specimen well of a test strip that has been inserted in the meter. Refer to the "CTR" section in the instructions for use for more information.

Note: The Renal Function Control Solution is intended for validating Renal Function testing while using the Renal Function Monitoring System. Both levels of control solutions must be tested and fall within the assigned values printed on the bottles.

Refer to the control solution package insert before using the controls. The control solution bottle is labeled with the acceptable range that is specific for that lot of control solution. The system is working properly if the control value displayed by the meter is within the acceptable range printed on the bottle label. If the value does not fall within the range, refer to the Control Solution Package Insert for further instructions.

RFM-101 insert 20191125.indd 12 2019/11/27 10:42:05

Precautions

Make sure the control solution and all the test materials reach operating temperature of 10 - 35°C prior to testing. The control solutions and test materials are only accurate within this temperature range.

Use the control solution before the expiration date shown on the bottle.

Discard the control solution if it appears cloudy.

Use the Renal Function Control Solution with the Renal Function Analysis Meter and test strip.

Storage and Handling

- Store the control solution either refrigerated or at room temperature 2 - 30°C.
- Do not freeze.
- If the control solution has been refrigerated, allow it to warm up to a temperature of 10 – 35°C before use.
- Each control solution will expire 3 months after the bottle is opened for the first time. Record this expiration date on the bottle label.

RFM-101 insert 20191125.indd 13 2019/11/27 10:42:05

Section 4 Initial Setup

Before testing, ensure the following procedures are followed.

Turn on Meter

Press ⏻ to turn the meter on.
The meter will automatically turn off after 5 minutes of inactivity.

Coding the Meter

Each time a new box of test strips is used, the new code chip included in the box must be inserted into the meter. Compare the code number on the code chip with the code number printed on the test strip box or the foil pouch. Results may be inaccurate if the two numbers are not identical. Insert the new code chip into the code chip slot of the meter. It should easily snap into place. The code chip should remain in the meter. Do not take it out until a new box of test strips is needed. The code number will appear on the Initial Screen after startup.
If the code chip is not properly inserted into the code chip slot or if it is missing, the meter will display E-6.

RFM-101 insert 20191125.indd 14 2019/11/27 10:42:05

Section 5 Meter Setup and Options

With the meter turned on, press ⏻ and hold for 2 seconds to enter the Setting mode. Press ◄ or ► to display several setup sub-modes.

SET
Press ⏻ to enter the SET item.

Year Setup
As the year is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Month Setup
As the month is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Day Setup
As the day is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Hour Setup
As the hour is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Minute Setup
As the minute is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Sound Setup
As the sound is diaplayed, press ◄ or ► to switch between On and oFF. Press ⏻ to save.

Bluetooth Setup
As the bluetooth is diaplayed, press ◄ or ► to switch between On and oFF. Press ⏻ to save.

Printer Setup
As the Printer is diaplayed, press ◄ or ► to switch between On and oFF.

RFM-101 insert 20191125.indd 15 2019/11/27 10:42:06

Press ⏻ to save.

Sample Select

As the sample shows FB, VB or SP, please press ⏻ to enter the Sample Set. Press ◄ or ► to switch between the Capillary Blood(FB), Venous Blood(VB) and Plasma and serum(SP).

Press ⏻ to save and enter the setup mode after selected.

⚠ **Caution: The Capillary Blood(FB) is the meter default.**

Note: The units are fixed as mmol/L or mg/dL.

RFM-101 insert 20191125.indd 16 2019/11/27 10:42:06

Section 6 Testing

The following steps show how to use each component to measure the sample concentration.

Specimen Collection

01. Use fresh capillary blood from the fingertip.
02. Use heparinized or EDTA venous whole blood. Please refer to Professional Testing below.

⚠ **Caution: Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a sufficient amount of blood are available.**

Testing with heparinized or EDTA venous whole blood, plasma and serum

For heparinized or EDTA venous whole blood, mix the specimen well, then collect specimen into a plastic/glass capillary transfer tubes or pipette. Apply it to the center region of the Specimen Application Area of the strip. Do not touch the test strips with the pipette or tube.

- Specimen must be tested within 8 hours after collection.
- Mix the specimens well before testing in order to ensure the cellular components are evenly distributed.
- Allow the specimen to come to operating temperature (10-35°C) for approximately 15 minutes if the specimen has been refrigerated.
- Anticoagulants other than EDTA and heparin are not recommended.

Note: Refer to NCCLS Documents H3-A6, Collection of Diagnostic Blood Specimens by venipuncture.

RFM-101 insert 20191125.indd 17 2019/11/27 10:42:06

Testing with fingertip blood

Wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Use a capillary transfer tube or pipette to collect capillary blood.

For use with the capillary transfer tube, hold the tube slightly downward and touch the tip of the capillary transfer tube to the blood specimen. Capillary action will automatically draw the specimen to the fill line and stop.

Note: The capillary transfer tube will fill automatically. Make sure the blood covers the air vent of the tube, or it will be difficult to squeeze the blood out. Never squeeze the capillary transfer tube while sampling.

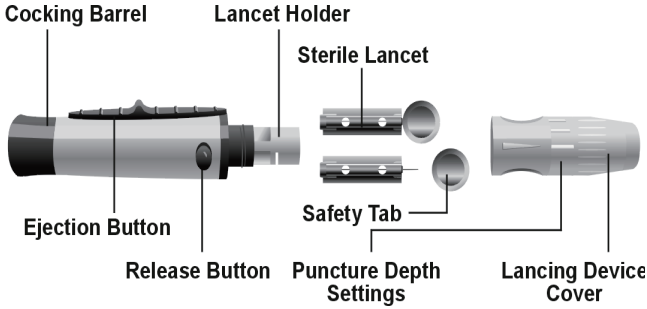
Align the tip of the capillary transfer tube with the center hole of the Specimen Application Area of the test strips to apply the second drop of blood.

Note: Do not touch the test strip with the capillary transfer tube or pipette. The capillary blood should be tested immediately after collected. Use of a capillary transfer tube or pipette is recommended for accurate results.

Blood specimens can be obtained by using a lancing device or a safety lancet.

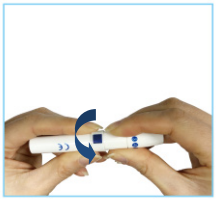
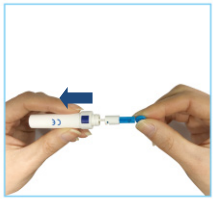
Note: Please use the safety lancet.

Lancing Device

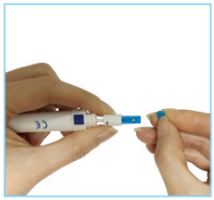


RFM-101 insert 20191125.indd 18 2019/11/27 10:42:06

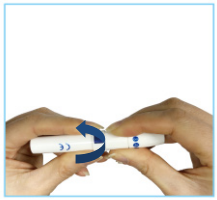
For obtaining a drop of blood from the fingertip, adjust the penetration depth on the lancing device to reduce discomfort.
Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.

Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Then pull the safety tab off of the lancet. Save the safety tab for lancet disposal.

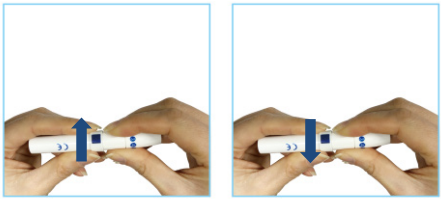


Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.



RFM-101 insert 20191125.indd 19 2019/11/27 10:42:06

Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.
Use settings 1 and 2 for delicate skin, 3 and 4 for normal skin, or 5 for calloused or thick skin.



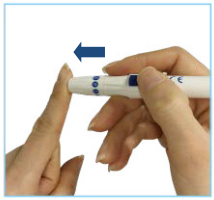
Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

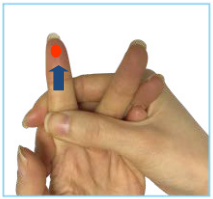
Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready to obtain a drop of blood.

Prior to testing, make sure the patient‘s hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.
Clean the testing site with an alcohol swab or by washing the hands with warm soapy water and then dry the testing site thoroughly.

RFM-101 insert 20191125.indd 20 2019/11/27 10:42:06

Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood. For the greatest reduction in pain, lance the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make the fingers sore and callused.





Note: Make sure the hand is warm and relaxed before collecting a capillary blood specimen. Use warm water to increase blood flow if necessary. Don't use an infection swab containing iodine. This can give inaccurate results.

Disposal of the Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Carefully insert the lancet needle into the safety tab.

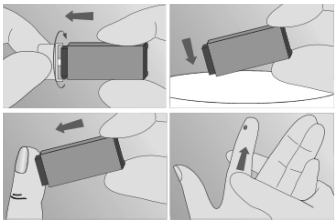
RFM-101 insert 20191125.indd 21 2019/11/27 10:42:07

Pull the used lancet off. Place the lancing device cover back on the lancing device.

Note: For professional use, please refer to NCCLS Documents H04-A6, Collection of Diagnostic Capillary Blood Specimens.

Safety Lancets

01. Carefully rotate and pull off the protective cap.
02. After cleaning the skin, hold the lancet firmly against the puncture site.
03. Press the lancet against the puncture site tightly to lance the skin. Discard the lancet in an appropriate sharps container.
04. Gently massage the surrounding area toward the puncture site to collect the required blood volume.



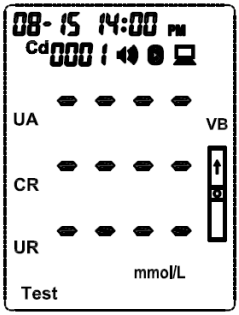
Test Processing

Ensure the meter is set up properly, as described in previous sections. Turn the meter on. Ensure the code chip is inserted. Compare the number showed in the display with the code number printed on the box label or foil pouch. The test strip icon flashes to indicate that it is ready for the strip to be inserted.

Check the specimen type is same as the specimen type tested. If not, set the

RFM-101 insert 20191125.indd 22 2019/11/27 10:42:07

correct specimen type.

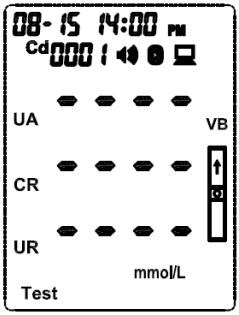


Testing

For use with a test strip, insert a strip into the Test Strip Holder in the same direction as the arrows indicate on the strip. Ensure that the test strip is inserted all the way to the end of the Test Strip Holder.

Note: For testing capillary blood, use the second drop of blood for accurate results.

The ***blood drop symbol*** will flash when the meter is ready for the specimen to be applied. Apply the blood specimen to the center region of the Specimen Application Area of the test strip.

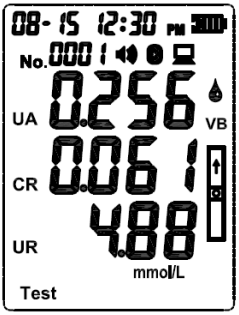


RFM-101 insert 20191125.indd 23 2019/11/27 10:42:07

Note: For testing capillary blood, use the second drop of blood for accurate results.

The meter will begin testing automatically with *four dashes* in a line flashing on the display indicating the test is in progress.

Results will be displayed within 300 seconds.



Note: The date in the display will be shown according to the mode you previously selected.

Remove the used test strip. The meter will return to the Initial Screen and is ready for another test strip to be inserted and to perform a new test.

Note: Discard all blood specimens, used Test strips, and materials carefully. Treat all blood specimens as if they were infectious material. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.

Perform daily cleaning when testing is completed for the day. Refer to the Maintenance section.

The meter will automatically turn off after 5 minutes of inactivity or when ⏻ is pressed.

RFM-101 insert 20191125.indd 24 2019/11/27 10:42:07

Section 7 Memory/Communication

Memory/Database

Press ⏻ to enter the MEM. Press ◄ or ► to display the latest 500 test records.

Deleting Data

To delete the data from the meter memory, press ◄ and ► at the same time to enable data deletion.

Press ⏻ to return to Setting screen.

Communication

If Bluetooth is turned on (the Bluetooth icon is displayed), when querying record at the MEM mode, the meter will send the current record to Bluetooth. If Printeris turned on (the Printer icon is displayed), when querying record at the MEM mode, the meter will print out the current.

RFM-101 insert 20191125.indd 25 2019/11/27 10:42:07

Section 8 Optical Verify Strip Test

After entering the ***CTR*** Mode, the meter will display ***OPt***. Press ⏻ and then insert a optical verify strip into the Test Strip Holder. Follow the direction of the arrows indicated on the strip. Ensure that the optical verify strip is inserted all the way.
The optical check will start automatically. If the meter displays ***OH***, the meter is normal. If the meter displays ***FL***, the meter is not functioning properly.

Note:

- The optical verify strip is intended to check the optical system.
- Allow the optical verify strips and the meter to reach operating temperature (10-35°C) prior to testing.
- The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

If the meter displays ***FL***, check the optical verify strip for contamination or to check if it is damaged. If there are any visible signs of damage or contamination, discard the optical verify strip and retest using new optical verify strip.

Remove the optical verify strip. The meter will return to the Initial Screen.

RFM-101 insert 20191125.indd 26 2019/11/27 10:42:07

Section 9 Quality Control

Each lab should use its own standards and procedures for performance. Test known specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements:

- When a new package of test strips is opened
- When a new operator uses the meter
- When test results seem inaccurate
- After performing maintenance or service on the meter

If quality control tests do not provide expected results, perform the following checks:

- Ensure that the test strips used are not expired.
- Ensure that the test strips are fresh from a new canister or package.
- Ensure that the controls are not expired.
- Repeat the test to ensure no errors were made during the test.

Control Solution Testing

Renal Function Control Solution testing is performed in a very similar manner to blood tests. The Renal Function Control Solution is used instead of blood.

Note: Make sure the control solution and all the test materials reach operating temperatures of 10-35°C prior to testing. Tests can only be accurately performed when the control solutions and test materials are within this temperature range.

01. Turn on the meter.
02. Insert the code chip into the meter. Refer to Coding the Meter in the instructions for use for details. Make sure the test strip box is firmly capped and the control solution is tightly closed before use.

RFM-101 insert 20191125.indd 27 2019/11/27 10:42:07

03. Compare the code number on the code chip with the code number printed on the test strip pouch label and ensure the two numbers are identical to avoid inaccurate results.

04. Press and hold ⏻ for 2 seconds to enter the Setting mode. And press ► to change the selection. Please press ⏻ to enter the ***CTR***. Press ◄ or ► to switch between ***OPt*** *and* ***SOLU***. Press ⏻ to confirm it and enter the ***SOLU*** after selected.

05. The meter will flash the test strip icon. Insert a test strip completely into the Test Strip Holder in the same direction as the arrows printed on the strip until it cannot be inserted any further.

06. When the meter is flashing the blood drop symbol, open the screw cap of the control solution bottle and turn the bottle upside down. Squeeze the control solution bottle gently and discard the first drop. If there are bubbles in the previous drop, squeeze the bottle and discard another drop until there are no bubbles in the drop. Apply the next drop to the specimen well on the test strip while keeping the bottle vertically upside down. Use about 35µL of control solution for the test strip. Make sure the control solution is applied directly into the specimen well and that there is no bubble in the solution drop.

Note:

- Make sure the bottle is completely vertical when applying the solution to the strip. The volume will be inconsistent if the bottle is not completely vertical.
- Gently squeeze the solution completely onto the tip of the bottle and drop it freely into the sample well. Avoid touching the strip with the tip of the bottle.

07. For the test, two kinds of control solutions need to be tested on two separate test strips. Remember to switch to a new test strip after the control solution has been tested on the first strip.

RFM-101 insert 20191125.indd 28 2019/11/27 10:42:07

Interpreting Results

The results should fall within the range(s) printed on the bottle label and are specific for each lot of controls. If the results fall within the specified control range, it indicates the Renal Function Analysis Meter is working correctly and the procedures are being performed properly.

If the results do not fall within the respective range(s), refer to the Control Solution Package Insert for further instructions.

RFM-101 insert 20191125.indd 29 2019/11/27 10:42:07

Section 10 Maintenance

Proper maintenance is recommended for best results.

General Cleaning

For best results, the meter should be cleaned after each day of testing.

Meter Surface

A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.

A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use.

Avoid getting liquids or residue entering the meter through the Test Strip Holder or Code Chip Slot.

Test strip Holder

Wipe it down with a damp cloth or a mild detergent. Dry it with a dry, soft cloth.

Meter Sensor Area

Wipe down the Test Strip Holder with a cotton swab. Do not scratch the transparent window covering the sensors.

⚠Caution: Do not use organic solvents, such as gasoline or paint thinner to clean the Test Strip Holder. This will cause damage to the meter.

RFM-101 insert 20191125.indd 30 2019/11/27 10:42:07

Cleaning Process

For best results, the meter should be cleaned after each day of testing.
A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.
A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use.
Take care to avoid getting liquids, residue, or control solutions in the meter through the Test Strip Holder, Code Chip Slot or USB Port.

Charging step

The meter is powered by lithium battery and can be charged by USB port. Connecting the Micro USB port to the meter, connecting the other end to the PC's USB port or adapter (output:5V ⎓ 0.5A), can charge the meter. The meter can not be tested when it is charging. Equipment with overcharge and over discharge protection device

⚠**Caution:The adapter or computer should meet the requirements of current edition of the IEC60950-1. Lithium batteries meet the standard requirements of the IEC62133:2012**

Battery Maintenance

Lithium batteries are built-in and cannot be disassembled.

- Meters should be stored in a cool, dry and safe environment.
- Avoid approaching the meter to heat source, open fire, flammable and explosive gas and liquid, otherwise it will lead to battery leakage, heating, smoking, ignition and explosion.
- If not used for a long time (more than a month), it is recommended to charge 40% - 60% of the battery

RFM-101 insert 20191125.indd 31 2019/11/27 10:42:07

Section 11 Precautions

Follow the precautions listed below to ensure accurate results and proper operation of the meter.

- The protection provided by the meter may be impaired if used in a manner not defined in this instruction manual.
- Wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Avoid storing or operating the meter in direct sunlight, excessive temperatures, or high humidity. Refer to Appendix 1 Meter Specifications for operating condition requirements.
- Keep the meter clean. Wipe it frequently with a soft, clean, and dry cloth. Use a damp cloth when needed.
- Do not clean the meter with substances, such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean, dry cloth.
- The test strip holder must be kept clean. Lightly wipe with a soft, clean, dry cloth before use. Use a damp cloth as needed. Refer to the Maintenance section.
- Follow all local regulations when discarding the meter or its accessories.
- Do not use the meter or the strip outside of the operating temperature ranges: 10-35°C; ≤ 80% RH.

RFM-101 insert 20191125.indd 32 2019/11/27 10:42:07

Section 12 Limitation

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	1324μmol/L(20mg/dL)	Cholesterol	12.9 mmol/L(500mg/dL)
Ascorbic Acid	568 μmol/L(10mg/dL)	Triglyceride	7.3 mmol/L(650mg/dL)
Conjugated Bilirubin	240 μmol/L(20mg/dL)	Uric Acid	0.6mmol/L(10mg/dL)
Creatinine	442 μmol/L(5mg/dL)	Hemoglobin	2 g/L(200mg/dL)
Ibuprofen	2425 μmol/L(50mg/dL)	Dopamine	5.87 μmol/L(0.09mg/dL)
Methyldopa	71 μmol/L(1.5mg/dL)		

High concentrations of uric acid and ascorbic acid can lead to low measurements. Anticoagulants,such as heparin and EDTA,are recommended for use with venous whole blood. Do not use EDTA plasma,which lead to higher results. Do not use other anticoagulants, such as iodoacetate,sodium citrate or those containing fluoride. Arterial blood isn't recommended for use.Hemolyzed blood or thrombolytic therapy blood may lower the results. Venous occlusion may increase the results and is not recommended to draw the blood.

RFM-101 insert 20191125.indd 33 2019/11/27 10:42:07

Section 13 Troubleshooting

Display	Causes	Solution
E-1	The sensor area is damaged, dirty, or blocked at turn-on, such as a used test strip left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to Maintenance. Restart the meter. Contact your local distributor if the sensor area window is broken.
E-2	Test strip was removed during the test.	Repeat the test and ensure the test strip remains in place.
E-3	Test strip expired.	Replace test strips and code chip. Check their expiry date.
E-4	Battery power is low. The meter can not be tested until it is charged.	Charging post-test.
E-6	Code chip was removed.	Insert proper code chip. Confirm the code chip matches the test strip code and repeat the test.
E-7	The environment temperature is higher than 35°C or lower than 10°C.	Get the meter in a proper environment where the temperature is between 10-35°C.
HI	The result is higher than the limited.	Retest with a new strip and contact your doctor.
Lo	The result is lower than the limited.	

RFM-101 insert 20191125.indd 34 2019/11/27 10:42:08

Section 14 Meter Performance

The Accuracy

Iterm	Range of sample	Bias
UA	0.090mmol/L-0.300mmol/L (1.51mg/dL-5.04mg/dL)	≤±0.060mmol/L (±1.01mg/dL)
	0.301mmol/L-1.200mmol/L (5.05mg/dL-20.17mg/dL)	≤±20%
CR	0.044mmol/L-0.150mmol/L (0.50mg/dL-1.70mg/dL)	≤±0.030mmol/L (±0.34mg/dL)
	0.151mmol/L-1.320mmol/L (1.71mg/dL-14.93mg/dL)	≤±20%
UR	0.90mmol/L-10.00mmol/L (5.41mg/dL-60.06mg/dL)	≤±2.00mmol/L (±12.01mg/dL)
	10.01mmol/L-40.00mmol/L(60.07mg/dL-240.24mg/dL)	≤±20%

The Precision

Iterm	Range of sample	SD
UA	0.090mmol/L-0.300mmol/L(1.51mg/dL-5.04mg/dL)	SD<0.023mmol/L (<0.38mg/dL)
	0.301mmol/L-1.200mmol/L (5.05mg/dL-20.17mg/dL)	CV<7.5%
CR	0.044mmol/L-0.150mmol/L (0.50mg/dL-1.70mg/dL)	SD<0.011mmol/L (<0.13mg/dL)
	0.151mmol/L-1.320mmol/L (1.71mg/dL-14.93mg/dL)	CV<7.5%
UR	0.90mmol/L-10.00mmol/L (5.41mg/dL-60.06mg/dL)	SD<0.75mmol/L (<4.50mg/dL)
	10.01mmol/L-40.00mmol/L(60.07mg/dL-240.24mg/dL)	CV<7.5%

RFM-101 insert 20191125.indd 35 2019/11/27 10:42:08

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	≤5 min
Measurement Range	UA: 0.090mmol/L-1.200mmol/L(1.51mg/dL-20.17mg/dL) CR: 0.044mmol/L-1.320mmol/L(0.50mg/dL-14.93mg/dL) UR: 0.90mmol/L-40.00mmol/L(5.41mg/dL-240.24mg/dL)
Specimen	Whole blood(capillary blood, venous whole blood), plasma and serum
Specimen Volume	35 µL or 10 µL
Power Source	Charging battery; Note: during charging, the meter is non-operational
Units of Measurement	mg/dL or mmol/L
Memory	500 records
Automatic Shut Off	After 5 minutes of inactivity
Meter Size	135 mm × 66mm × 19 mm
Weight	90g
Meter storage and transportation t conditions	0°C - 55°C; ≤ 90% RH
System Operating Conditions	10°C - 35°C; ≤ 80% RH; indoor only
pollution degree of the intended environment	2
System operating altitude	Max. 2000 m
Test strip storage and transportation t conditions	2°C - 30°C; ≤ 90% RH
Optical Verify Strip storage and transportation t conditions	2°C - 30°C; ≤ 90% RH
Meter Software Version Number	1.0

RFM-101 insert 20191125.indd 36 2019/11/27 10:42:08

Appendix 2 Labelling And Information

	Do not reuse		Use by
	Keep dry		Manufacturer
	CE marking	LOT	Batch code
	Biological risks	REF	Catalogue number
	Consult instructions use		

EC REP Authorised representative in the European Community

IVD In vitro diagnostic medical device

Caution, the user must be consulted in all cases where this symbol is marked

Symbol for the marking of electrical and electronics devices according to Directive 2012/19/EU.The device accessories and the packaging have to be disposed of waste correctly at the end of the usage.Pleases follow Local Ordinances of Regulations for disposal

RFM-101 insert 20191125.indd 37 2019/11/27 10:42:08

Appendix 3 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within 30 days of purchase.

Note: This warranty applies only to the meter in the original purchase. It does not apply to the other materials included with the meter.

Hangzhou Lysun Biotechnology Co., Ltd. warrants to the original purchaser that this meter will be free from defects in materials and workmanship for a period of two years (24 months) since the latest date of original purchase or installation, except as noted below. Within the prescribed two years, Lysun Biotechnology Co., Ltd. shall replace the meter under warranty with a reconditioned meter, at its option, repair at no charge if a meter that is found to be defective. Lysun Biotechnology Co., Ltd. shall not be responsible for shipping charges incurred in the repair of a meter.

This warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. Lysun Biotechnology Co., Ltd. shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the meter in accordance with the user's manual, or maintenance by anyone other than Lysun Biotechnology Co., Ltd. Furthermore, Lysun Biotechnology Co., Ltd. assumes no liability from malfunction or damage to meters caused by the use of devices other than devices manufactured by Lysun Biotechnology Co., Ltd. Lysun Biotechnology Co., Ltd. reserves the right to make changes in the design of this meter without obligation to incorporate such changes into previously manufactured meters.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties expressed

RFM-101 insert 20191125.indd 38 2019/11/27 10:42:08

or implied (either in fact or by operation of law), including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by Lysun Biotechnology Co., Ltd.

Limitations of Liability

In no event shall Lysun Biotechnology Co., Ltd. be liable for indirect, special or consequential damages, even if Lysun Biotechnology Co., Ltd. has been advised of the possibility of such damages. For warranty service, please contact your local distributor.

Hangzhou Lysun Biotechnology Co., Ltd.
6th Floor, 6th Building, No.95 Binwen Road, Xixing Street,Binjiang District,Hangzhou,Zhejiang,P.R. China
Tel: 0086-571-86716518

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Printed in China. Effective date: 2019-02-23

RFM-101 insert 20191125.indd 39 2019/11/27 10:42:08