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isaw[®]

Multi-Monitoring Meters

Quick and accurate multiparameter

Total Cholesterol

Blood Glucose

Hemoglobin

Uric Acid



isaw[®]

Multi-Monitoring Meters Owner:

User's Manual

Dear *isaw*[®] Multi-Monitoring Meters Owner:

isaw[®] is a diagnostic aid multiparameter with capillary aspiration for the determination of the following parameters:

Total Cholesterol

Blood Glucose

Hemoglobin

Uric Acid

We designed this product to enable you check your total cholesterol, uric acid, blood glucose and hemoglobin in one meter. This fast, accurate, and powerful system helps you check your health easily using its expert multi-functions. The *isaw*[®] meter uses leading amperometric technology in a unique electrochemical process.

It gives you fast detection in a few seconds, less blood is needed which means less pain, easy carrying and multi-function which gives you a full health check solution in one meter.

This User's Manual designed to provide the information that you are looking for when you need it. We hope you keep it handy.

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Your *isaw*® Multi-Monitoring Meters

Before You Begin

Before using this product to test your total cholesterol, uric acid, blood glucose and hemoglobin, carefully read this user's manual and the insert come with the *isaw*® test strips. Take note of warnings and cautions throughout this user's manual, which are identified with ⚠.

Intended Use

The *isaw*® Multi-Monitoring Meters is intended to be used for quantitative measurement of total cholesterol, blood glucose, hemoglobin and uric acid in fresh capillary whole blood and venous whole blood. Test results of total cholesterol, blood glucose, hemoglobin and uric acid are plasma-calibrated. This helps you and your healthcare professional to compare your meter results with laboratory tests.

Measuring Principles

The *isaw*® Multi-Monitoring Meters employs electrochemical biosensor technology to measure an enzymatic chemical reaction. When blood is applied to an electrochemical test strip, an electrical current is produced. The Multi-meter measures the current and calculates the level, displays the result, and stores the result in its memory.

Your *isaw*® Multi-Monitoring System Kit includes:

1. *isaw*® Multi-Monitoring Meter (model: LBM-01)
2. *isaw*® Uric Acid Test Strips (model: UA01) optional
3. *isaw*® Blood Glucose Test Strips (model: BG01) optional
4. *isaw*® Total Cholesterol Test Strips (model: TC01) optional
5. *isaw*® Hemoglobin Test Strips (model: HB01) optional
6. Lancing Device
7. Sterile Lancets
8. User's Manual
9. Carrying Case



Note: Do not expose the meter or any of the supplies or accessories to high humidity, extreme heat, cold, dust, or dirt. The meter may be stored at a temperature of -20°C and +50°C and 20-80% Relative Humidity (RH). Store the kit(meter and test strips) at a temperature 2-30°C. If storage temperature is below 20°C or above 30°C, allow the meter to warm to room temperature 20-25°C before using. If the meter has been stored under excessive conditions, allow at least 30 minutes at room temperature for the device to equilibrate to these temperatures .

⚠ The use of this instrument in a dry environment, especially in the presence of synthetic materials (clothing, synthetic carpets, etc.), may cause harmful electrostatic discharges and lead to erroneous results. This device complies with the emission and immunity requirements described in EN 61326-1 and EN 61326-2-6. Do not use the device near strong electromagnetic radiation sources, as this may interfere with its normal operation.

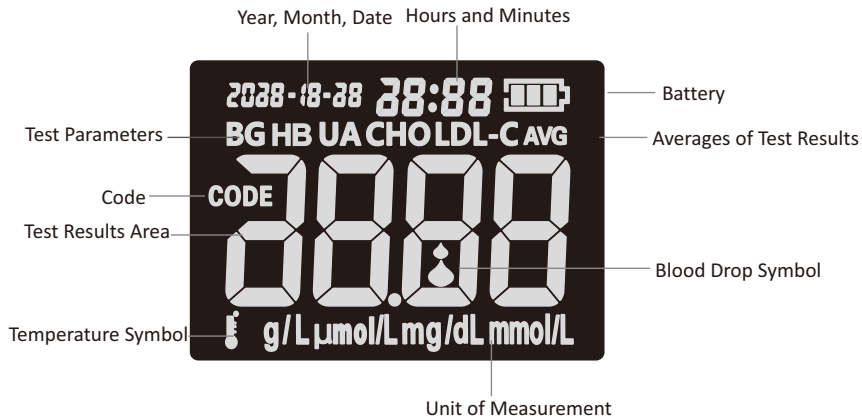
Chapter 1 Understanding Your Meter

The *isaw*® Multi-Monitoring Meter



1. Measuring port; 2. C Button; 3. M Button; 4. Display; 5. Ejection button
1. Measuring port- Insert test strip here to turn meter on for testing
2. C Button-Used to change date and time, code number and review test results in memory
3. M Button- Used to turn meter on to enter setting mode and memory mode.
4. Display-Symbols, Simple message and test results appear here.
5. Ejection button- Press here to eject the used strip out.

Meter Display Information



mg/dL (mmol/L) is the pre-set unit of measurement

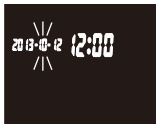
Setting the Meter Year, Month, Date and Time

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

To set the time, you must enter the setting mode. Start with the meter off. Then press and hold the M button for three seconds. The meter is now in the setting mode with the year setting flashing, press and release the C button down. With the correct year on the display, press the M button and the month setting will start flashing.



Press and release the C button to advance one month. With the correct month on the display, press the M button and the day segment will start flashing.



Press and release C button to advance one day. With the correct day on the display, press the M button and the hour segment will start flashing.



The meter display the time in an 24-hour format, press and release the C button to advance one hour. With the correct hour on the display, press the M button and the minutes segment will start flashing.



Press and release C button to advance one minute. With the correct minutes on the display, press the M button and exiting the setting mode.

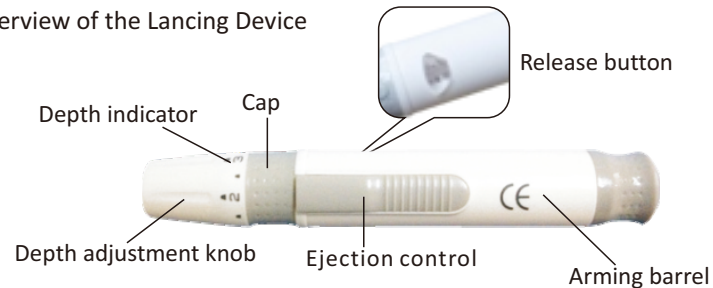


⚠ Note : You must move through the year, month, day, hour and minutes to turn off the meter and exit the setting mode.

Chapter 2 Starting the Test Process

Getting a Blood Sample

Overview of the Lancing Device



The lancet is composed of lancet point, lancet body, protective disk and protective disk.



How to Get Blood Sample

a. Remove the cap by twisting it off.



b. Insert the lancet into the holder and push in firmly.



c. Twist the protective disk until it separates from the lancet and save the disk for later use. Do not twist the lancet.



d. Replace the cap by twisting it back on until it is snug.



e. If necessary, twist the depth adjustment knob toward the smaller dots on the lanceting device for a shallow puncture or toward the larger dots for a deeper puncture. Hold end cap in one hand and arming barrel in other. Gently pull arming barrel until a click is heard.



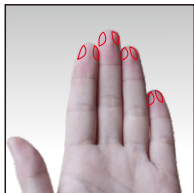
f. Wash your hands thoroughly with warm, soapy water. Rinse and dry, if you use the alcohol pad to disinfect your finger, you should wait the alcohol evaporating completely. Let your arm drop for 10-15 seconds will be helpful to sampling.



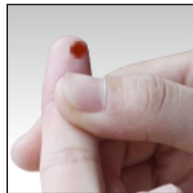
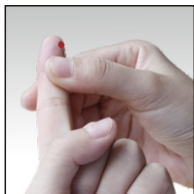
For best results, sampling against the side of your finger, each different position will prevent the fingers to fester and thickening.



g. Hold the lancing device firmly against the side of your finger. Press the release button, remove the lancing device from your finger.



h. Gently squeeze and/or massage your fingertip until a round drop of blood of at least 1.5 microliter forms on your fingertip.



If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop of blood or puncture a new site.

i. Remove the lancing device cap by twisting it off. Then, place the lancet protective disk on a hard surface. Push the lancet tip into the disk, push forward on the ejection button and the lancet will come out. Pull back the ejection button. Replace the cap.



⚠ Important: It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal. If share the lancing device with others, please sterilize the lancing device cap with 75% alcohol. Be sure to use a new lancet.

⚠ **Note:** Please refer to the instructions that came with your lancing device.

⚠ **CAUTION:** ALWAYS use a new, sterile lancet each time you test. NEVER reuse a lancet that has already been used.

Match the Code Numbers

1. Code numbers are used to calibrate your meter with the test strips you are using. Please check the code on the test strip vial before inserting the strip.



2. Insert a test strip to turn on the meter. Insert the test strip into the test port as shown. Make sure the three contact bars are facing you. Push the strip in as far as it will go. Do not bend the strip. The meter will display the code on the meter display, if the code on the meter does not match the code on the test strip vial, press C button to match the code number on the test strip vial.

The new code number will flash on the display for three seconds, then briefly stop flashing, then the symbol ▲ will appear, indicating the meter is ready for testing.



If the codes already match, you do not make a change after five seconds, the symbol ▲ will appear, indicating the meter is ready for testing.

⚠ **CAUTION:** Matching the code on the meter with the code on the test strip vial is essential to obtaining accurate results. Each time you test, check to make sure the code numbers match. Use each test strip immediately after removing it from the vial.

Total Cholesterol Testing

1. Insert a test strip to turn on the meter
Start with the meter off. Remove a cholesterol test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way.



Use each test strip immediately after removing it from the vial. Insert the test strip into the test port as shown. The meter will display CHO with the code number. The meter will remember the code from your last test. Match the code (please see page 15), after 5 seconds, the meter display CHO with  symbol, the meter is now ready to perform a total cholesterol test.

2. Apply the sample

Once you have a blood sample and your meter shows the CHO and  Symbol, touch and hold the drop of blood to the narrow channel in the top edge of the test strip.



Blood will be drawn into the strip. Keep holding the drop of blood to the top edge of the test strip until the confirmation window is full.



3. Read your total cholesterol test result
When the meter detects blood in the test strip, it begins to count down from 15 to 0. Then, your total cholesterol level appears on the display, along with the unit of measure, and the date and time of the test. Total cholesterol results are automatically stored in the meter's memory.

4. After getting a result, turn the meter off by removing the test strip.

5. Disposing of the used lancet and test strip

It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

Uric Acid Testing

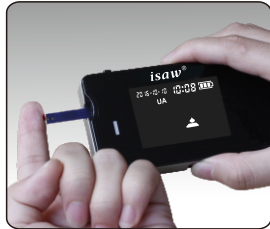
1. Insert a test strip to turn on the meter
Start with the meter off. Remove a uric acid test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial.



Insert the test strip into the test port as shown. The meter will display UA with the code number. The meter will remember the code from your last test. Match the code (please see page 15), after 5 seconds, the meter display UA with symbol Δ , the meter is now ready to perform a uric acid test.

2. Apply the sample

Once you have a blood sample and your meter shows the UA and  Symbol, touch and hold the drop of blood to the narrow channel in the top edge of the test strip.



Blood will be drawn into the strip. Keep holding the drop of blood to the top edge of the test strip until the confirmation window is full.

3. Read your uric acid test result

When the meter detects blood in the test strip, it begins to count down from 5 to 0. Then, your uric acid level appears on the display, along with the unit of measure, and the date and time of the test. Uric acid results are automatically stored in the meter's memory.



4. After getting a result, turn the meter off by press the ejection button to remove the test strip.

5. Disposing of the used lancet and test strip

It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

Blood Glucose Testing

1. Insert a test strip to turn on the meter
Start with the meter off. Remove a blood glucose test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial. Insert the test strip into the test port as shown. The meter will display BG with the code number. The meter will remember the code from your last test. Match the code (please see page 15), after 5 seconds, the meter display BG with symbol ▲, the meter is now ready to perform a blood glucose test.



2. Apply the sample

Once you have a blood sample and your meter shows the BG and ▲ Symbol, touch and hold the drop of blood to the narrow channel in the top edge of the test strip. Blood will be drawn into the strip. Keep holding the drop of blood to the top edge of the test strip until the confirmation window is full.



Note:

Do not smear or scrape the drop of blood with the test strip.
Do not press the test strip too firmly against your puncture site.
Do not apply more blood to the test strip after you have moved the drop of blood away.
Do not move the test strip in the meter during a test.

3. Read your blood glucose test result
When the meter detects blood in the test strip, it begins to count down from 5 to 0.



Then, your blood glucose level appears on the display, along with the unit of measure, and the date and time of the test. Blood glucose results are automatically stored in the meter's memory.

4. After getting a result, turn the meter off by press the ejection button to remove the test strip.



5. Disposing of the used lancet and test strip

It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

Hemoglobin Testing

1. Insert a test strip to turn on the meter

Start with the meter off. Remove a Hemoglobin test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial. Insert the test strip into the test port as shown. The meter will display HB with the code number. The meter will remember the code from your last test. Match the code (please see page 15), after 5 seconds, the meter display HB with symbol ▲, the meter is now ready to perform a Hemoglobin test.





2. Apply the sample

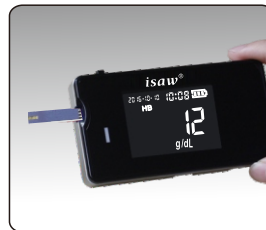
Once you have a blood sample and your meter shows the HB and  Symbol, touch and hold the drop of blood to the narrow channel in the top edge of the test strip. Blood will be drawn into the strip. Keep holding the drop of blood to the top edge of the test strip until the confirmation window is full.

Note:

- Do not smear or scrape the drop of blood with the test strip.
- Do not press the test strip too firmly against your puncture site.
- Do not apply more blood to the test strip after you have moved the drop of blood away.
- Do not move the test strip in the meter during a test.

3. Read your Hemoglobin test result

When the meter detects blood in the test strip, it begins to count down from 5 to 0.



Then, your Hemoglobin level appears on the display, along with the unit of measure, and the date and time of the test. Hemoglobin results are automatically stored in the meter's memory.

4. After getting a result, turn the meter off by press the ejection button to remove the test strip.

5. Disposing of the used lancet and test strip

It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

Chapter 3: Reviewing Past Results and Averages

Reviewing Total Cholesterol Test Results

Press and hold M button to turn on the meter, press and release C button, until the CHO show on display, press the M button, 7-day, 14-day and 28-day average and the most recent test result with date and time will appear. Press and release the C button and the next most recent test result will appear. The meter will recall up to your last 100 total cholesterol test results in order from most recent to the oldest. When the memory is full, the oldest result is dropped and the newest is added. Press the M button to turn off the meter.



Reviewing Uric Acid Test Results

Press and hold M button to turn on the meter, press and release C button, until UA show on display, press the M button, 7-day, 14-day and 28-day average and the most recent test result with date and time will appear. Press and release the C button and the next most recent test result will appear. The meter will recall up to your last 100 uric acid test results in order from most recent to the oldest. When the memory is full, the oldest result is dropped and the newest is added. Press the M button to turn off the meter.



Reviewing Blood Glucose Test Results

Press and hold M button to turn on the meter, press and release button the C button, until BG show on display, press the M button, 7-day, 14-day and 28-day average and the most recent test result with date and time will appear. Press and release the C button and the next most recent test result will appear. The meter will recall up to your last 100 blood glucose test results in order from most recent to the oldest. When the memory is full, the oldest result is dropped and the newest is added. Press the M button to turn off the meter.



Reviewing Hemoglobin Test Results

Press and hold M button to turn on the meter. The display will show HB, press the M button, 7-day, 14-day and 28-day average and the most recent test result with date and time will appear. Press and release the C button and the next most recent test result will appear. The meter will recall up to your last 100 hemoglobin test results in order from most recent to the oldest. When the memory is full, the oldest result is dropped and the newest is added. Press the M button to turn off the meter.



Chapter 4: Caring for Your Meters

How to Clean and Disinfect the Meter

1. Wash hands thoroughly with soap and water.



2. Turn off the meter and wipe the entire meter surface with an approved cleaning and disinfecting product. Always use the same product for both cleaning and disinfecting.

3. Carefully wipe around the test strip slot and other openings. Make sure that no liquid enters any slot or opening.





4. Dry the meter with a soft cloth or gauze. Make sure that no solution is seen in any slot or opening.

5. For disinfecting the meter, get a new wipe or cloth. Repeat steps 2 and 3 following the manufacturer's instructions for disinfecting.



6. Wash hands thoroughly with soap and water.

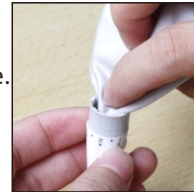
How to Clean and Disinfect the Lancing Device

1. Wash hands thoroughly with soap and water.



2. Wipe the entire surface of the lancing device and the inside of the lancing device cap with an approved cleaning and disinfecting product. Always use the same product for both cleaning and disinfecting.

3. Dry the lancing device and cap with a soft cloth or gauze. Make sure no solution is seen in any opening.





4. For disinfecting the lancing device, get a new wipe or cloth. Repeat step 2 following the manufacturer's instructions for disinfecting.

5. Wash hands thoroughly with soap and water.



Caring for Your Meters

- Take care to avoid getting dirt, dust, blood, control solution, or liquids inside the meter through the test port.
- It is recommended that you store the meter in its carrying case after each use.

- To clean your meter, make sure the meter is turn off, wipe the outside with a soft cloth dampened with water and mild detergent. Do not use alcohol or another solvent to clean your meter.
- Yours *isaw*® meter is a precision instrument. Please handle it with care, force free throw will cause the electronic devices within the instrument damage.
- Store each items in a cool, dry place below 30°C, but do not refrigerate. Keep all items away from direct sunlight and heat.
- Keep the meter away from moisture, any liquids or battery leakage coming inside the meter may cause permanent failure, we recommend regular inspection.
- Do not disassemble the meter, improper disassembly may cause malfunction of precision components and test results wrong, and thus lead to the termination of the warranty period.

Important information

- The system should be used in a dry environment, humid air and corrosive gases will cause damage to the system.
- The system should be used under natural light conditions, to avoid direct sunlight.

- Please use the meter between 10°C-40°C, if the temperature is above or below the proper range for the system. Stop the testing, move to an area with the appropriate conditions, wait 5 minutes, and repeat the test. Do not artificially heat or cool the meter.
- The meter should be avoided frequent switching power supply, power off and power on the interval should be at least 5 seconds, otherwise the meter will cause the device due to the current vulnerability of repeated shocks.
- You should gradually follow the requirements of the operating instructions when changing the meter settings.
- Ensure your safety and proper operation of the meter, please use the battery produced by manufacturers who are in compliance with the formal requirements of national security.
- During normal testing, any meter or lancing device may come in contact with blood. All part of the meter and lancing device are considered biohazardous and can potentially transmit infections. It is recommended to wear protective gloves when clean and disinfect the meter and lancing device.

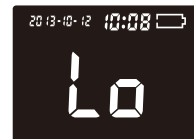
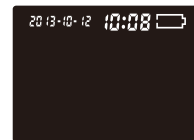
Power Supply

Your *isaw*® Multi-Monitoring Meter uses DC 3V (2 AAA Batteries) . Replacement batteries can be found in most stores.

Low meter battery

The meter shows battery icon () in the upper right corner of the display or a low battery message to indicate the condition of the meter batteries only. When the battery icon first appears, there is enough power for a minimum of 100 more tests. You should replace the meter batteries as soon as possible.

When your meter displays the battery icon () with LO, there is not enough battery power remaining to perform a test. You must install new batteries before using your meter.



Replacing Batteries

1. Remove the old batteries

Start with the meter off. Open the battery door and get the old batteries out.

2. Insert the new battery

Distinguish the positive and negative of battery, and place the batteries in the compartment. If the meter does not power on after you have replace the meter batteries, check that the batteries are correctly installed. If the meter still does not power on, call Customer Service.

3. Check your meter setting.

Removing the meter batteries will not affect your stored results. However, you may need to re-set your meter settings.

4. Dispose of batteries according to your local environment regulations.



Power supply with portable power pack

Contact portable power pack with meter, then turn on the portable power pack, then insert the test strip and start to test.

Display Messages and Problem-Solving Guide

The *isaw*® Meter displays messages when there are problems with the test strip, with the meter. Improper use may cause an inaccurate result with producing an error message.

1. Error message could be caused either by a used test strip or a expired test strip. Repeat the test with a new test strip. If this message continues to appear, Contact Customer Service.



2. Error message that indicates that blood or control solution sample was applied before the symbol ▲ appeared on the display. Repeat the test with a new test strip. Apply blood or control solution sample after symbol ▲ appears on the display.

3. Error message that indicates that not enough blood, or control solution was drawn into the test strip for measurement. Discard the strip and re-start the test process. If the error message appears again, Contact Customer Service.



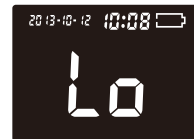
4. Message that indicates that the temperature is above or below the proper range for the system. Please use the meter between 10°C-40°C.

5. Move to an area with the appropriate conditions, wait 5 minutes, and repeat the test. Do not artificially heat or cool the meter. If the message appears again, Contact Customer Service.



6. The battery is low but still has enough power to perform a test.

7. The battery is almost out of power. Please change the battery now. If the message appears again, Contact Customer Service.



8. An electronic error occurred or, in rare cases, a used test strip was removed and reinserted. Turn the meter off and on or take the battery out for 20 seconds and reinsert it. Perform a blood glucose or control test. If the problem persists, contact the Customer Care Service .

Technical Parameter

Power supply: DC 3V (2 AAA Batteries);
Measuring speed: Total cholesterol 15 sec; Uric acid 5 sec;
Blood glucose 5 sec; Hemoglobin 5 sec;
Measuring principle: Biosensor Technology;
Correcting code of Total cholesterol test strips: 1-49;
Correcting code of uric acid test strips: 1-49;
Correcting code of blood glucose test strips: 1-49;
Correcting code of Hemoglobin test strips: 1-49;

Measuring range:

Total cholesterol: 100-400mg/dL (2.5-10mmol/L);
Uric Acid: 1.5-19.83mg/dL (90-1190 μ mol/L);
Blood glucose: 20-600mg/dL (1.1-33.3mmo/L);
hemoglobin: 5-26g/dL (3.1-16.12mmol/L);
Sample volume: blood sample about 1-2 μ L blood;
Sample: capillary whole blood and venous whole blood;

Size: 111mm×59mm×16mm

Warranty: 5 years;

Weight: 110g

Range of Expected Values

1. Range of Expected Values for Total Cholesterol
100-208mg/dL (2.5-5.2mmol/L)

2. Range of Expected Values for Uric Acid
Male: 2.5-6.9 mg/dL (149-416 μ mol/L),
Female: 1.5-5.95mg/dL (90-357 μ mol/L).

3. Range of Expected Values For Blood Glucose

Time	Range, mmol/L	Range, mg/dL
Before breakfast	3.9-5.8	70-105
Before lunch or dinner	3.9-6.1	70-110
1 hour after meals	Less than 8.9	Less than 160
2 hours after meals	Less than 6.7	Less than 120
Between 2 and 4AM	Greater than 3.9	Greater than 70

4. Range of Expected Values for Hemoglobin

Male: 13-18g/dL (8-11mmol/L)

Female: 11.5-16.5g/dL (7.1-10.2mmol/L)

Precautions to Obtain Accurate Results

Keep the system Cleaned and Disinfected

Don't smear the blood sample.

Don't use the expired test strip.

Match the code on the meter with the code on the test strip vial.

Contact your healthcare professional regularly.

Warranty

Royalzyze Medical warrants to the original purchaser of the meter that your *isaw*[®] meter will be free from defects in materials and workmanship for five years from the date of purchase. If, during this five-year period, the meter does not work properly because of a defect in materials or workmanship, Royalzyze Medical will replace it with a new *isaw*[®] meter free of charge. The warranty on the replacement meter will expire on the date of the original warranty expiration or 90 days after the shipment of a replacement system, whichever period is longer. The purchaser's exclusive remedy with respect to the *isaw*[®] meter shall be replacement.

This warranty does not apply to the performance of an *isaw*[®] meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. Royalzyze Medical will handle meters that show damage or abuse according to its Non-Warranty Service Policy described on the following page. The above warranty is exclusive of all other warranties, and Royalzyze Medical makes no other warranties, express or implied, including without limitation, the implied warranty of merchantability or fitness for a particular purpose.

In no event shall Royalzyze Medical be liable to the purchaser or any other person for any incidental, consequential, indirect, special, or punitive damages arising from or in any way connected with the purchase or operation of the meter or its parts.

Notes on Symbols and Marks

	In vitro diagnostic medical device		Protect from heat and radioactive sources
	Caution		Keep dry
	Manufacturer		Keep away from sunlight
	Date of manufacture		Biological risks
	Batch code		Temperature limit
	Consult instructions for use		Conformity with Directive 98/79/EC
	Serial number		Authorized representative in the European Community / European Union
	Indicates this device is subject to the Waste Electrical and Electronic Equipment (WEEE) Directive in the European Union		