Romed®

Blood Glucose Monitoring System

REF: BGM-60

User Guide

www.romed.nl

CE 0197

IVD	For *In vitro* diagnostic use		Temperature limitation / Store at
	Please consult instructions for use		Use by / Expiry date
	Do not reuse		Manufacturer
LOT	Lot number		Caution, consult accompanying document
	Keep dry		Keep away from sunlight
	Humidity limitation	MD	Medical device

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Romed Manufacturer

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SIDE A

Before You Begin

PLEASE READ THIS BEFORE USING.

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
2. Use the device only for the intended use described in this manual.
3. Do not use test strips and control solutions which are not supplied by the manufacturer.
4. Do not use the device if it is not working properly, or if it has suffered any damage.
5. Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.
6. 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.
7. Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
8. KEEP THESE USER GUIDE WITH YOU.

Intended Use

IVD The system is intended for use outside the body (*in vitro* diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

Principle of Measurement

Blood glucose is measured by an electrical current that is produced when a blood samples mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The Romed meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L).

⚠ Caution

1. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
2. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
3. High altitudes above than 3,402 meter (11,161 ft) may affect the test results.
4. Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results. Do not test beyond of temperature range.

⚠ IMPORTANT HEALTH-RELATED INFORMATION

1. Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
3. Test results below 60 mg/dL (3.3 mmol/L)*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)*2 indicates high blood glucose (hyperglycemia).If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.
4. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
5. Abnormal red blood cell counts (hematocrit level below 20% or above 60%) may cause false results. Please consult your healthcare professional if you do not know your hematocrit level.
6. Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect Romed test results. However, elevated concentrations of these substances may affect test results. The compounds listed in the tables were found to have no affect at the concentration indicated.

Compounds	Concentrations higher than the following values may cause inaccurate results	Compounds	Concentrations higher than the following values may cause inaccurate results
Acetaminophen	8.0 mg/dL (0.53 mmol/L)	Hydroxyurea	3.0 mg/dL (0.39 mmol/L)
Ascorbic Acid	5.0 mg/dL (0.28 mmol/L)	Ibuprofen	50 mg/dL (2.42 mmol/L)
Aspirin	60 mg/dL (3.33 mmol/L)	Icodextrin	13 mg/dL (0.01 mmol/L)
Bilirubin	90 mg/dL (1.54 mmol/L)	L-dopa	10 mg/dL (0.51 mmol/L)
Cholesterol	500 mg/dL (12.9 mmol/L)	Maltose	900 mg/dL (26.3 mmol/L)
Creatinine	5.0 mg/dL (0.44 mmol/L)	Methyldopa	3.0 mg/dL (0.13 mmol/L)
Dopamine	2.0 mg/dL (0.11 mmol/L)	Pralidoxime Iodide	25 mg/dL (0.94 mmol/L)
EDTA	360 mg/dL (12.3 mmol/L)	Salicylate	60 mg/dL (4.34 mmol/L)
Galactose	900 mg/dL (50 mmol/L)	Tolazamide	100 mg/dL (3.21 mmol/L)
Gentisic Acid	5.0 mg/dL (0.32 mmol/L)	Tolbutamide	400 mg/dL (14.8 mmol/L)
Glutathione	53 mg/dL (1.72 mmol/L)	Triglycerides	2,000 mg/dL (22.6 mmol/L)
Haemoglobin	500 mg/dL (0.08 mmol/L)	Uric Acid	8.0 mg/dL (0.48 mmol/L)
Heparin	8,000 U/dL	Xylose	100 mg/dL (6.66 mmol/L)

REFERENCE:
* 1: Kahn, R. and Weir, G. : Joslins Diabetes Mellitus, 13thed Philadelphia : Lea and Febiger (1994). 489.
* 2: Krall, L.P. and Beaser, R. S.: Joslin Diabetes Manual. Philadelphia : Lea and Febiger(1989), 261-263.

1. Getting To Know Your System

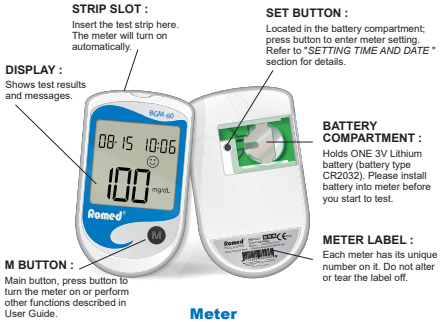
The Romed Blood Glucose Monitoring System.

The Romed system uses the latest technology to provide you with easy and comfortable testing. The system requires only a 0.7 µL of blood sample to complete the testing in only 6 seconds.

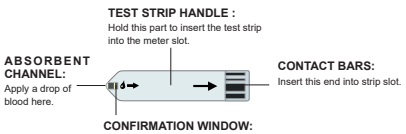
The Romed system consists of

1. Romed Blood Glucose Meter
2. Romed Blood Glucose Test Strips
3. Romed Control Solution

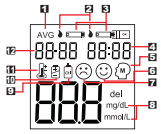
Important : Use only Romed test strips and control solutions with your Romed meter. Use other test strips and control solutions with this meter can produce inaccurate results.



Meter



Test Strip



1. **AVERAGE** : Appears when the meter is in the memory mode while recalling 7/14/21/28 day test averages.
2. **BLOOD DROP SYMBOL** : Flashes when sample should be applied.
3. **STRIP SYMBOL :** Appears when the meter is turned on and waiting for inserting a test strip.
4. **TIME :** The meter is programmed for a 24 hour period format.
5. **MEMORY SYMBOL :** Appears when in the memory mode.
6. ☺ : Appears when test result is within the range of 70 to 120 mg/dL (3.9-6.7 mmol/L)
7. ☹ : Appears when test result is lower than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10 mmol/L)
8. **UNIT OF MEASURE :** Appears with the test result in mg/dL.
9. **CONTROL SOLUTION TEST SYMBOL :** Appears when you are in Control Solution Mode. Your test result will not be stored in meter memory.
10. **BATTERY SYMBOL:** Appears when battery is weak.
11. **THERMOMETER SYMBOL :** Appears when ambient temperature is above or below the acceptable range needed for testing.
12. **DATE :** Display year, month and date.

REPLACING THE BATTERY

The Romed comes with ONE Lithium battery (battery type CR2032) .

Battery life will vary depending on usage, so always keep a spare battery on hand. The battery should last about 1000 tests or 12 months when testing 3 times a day.

When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace it as soon as possible.

When battery symbol and E-b shows up in the meter display, the meter will no longer give results and you must replace the battery immediately. Please always have one spare battery with you to ensure that you can replace the battery anytime.

How to replace the battery

	1. Make sure the meter is turned off. Let the front of the meter rest in the palm of your hand. Slide battery cover open.
	2. Use the edge of battery cover to pull out battery from the battery holder.
	3. Insert new battery (battery type CR2032), being sure to align the plus (+) side up. You should hear a beep to indicate the battery installed correctly. If not, please reinsert the battery correctly.
	4. Close battery cover.

⚠ **NOTE:**

1. Replacing the battery does not affect the test result stored in memory. However the time and date may need to re-set.
2. As with all small objects, the battery should be kept away from small children as a safety precaution. If the battery is swallowed, seek medical assistance immediately.
3. Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for extended (i.e., 3 months or more).
4. Please discard the product or the batteries properly according to the regulations of your country.

SETTING TIME AND DATE

Please install battery first and set correct time and date before you begin to test.

	**STEP 1. Enter Setting Mode** Start with the meter off. Open the battery compartment, and press SET BUTTON. The meter will turn on and enter the setting mode.
	**STEP 2. Set the Year** The year appears with the number flashing. Press and release the M BUTTON to obtain the desired year. Press SET BUTTON to confirm and move to next MONTH setting.
	**STEP 3. Set the Month** The month appears with the number flashing. Press and release the M BUTTON to obtain the desired month. Press SET BUTTON to confirm and move to next DATE setting.
	**STEP 4. Set the Date** The date appears with the number flashing. Press and release the M BUTTON to obtain the desired date. Press SET BUTTON to confirm and move to next HOUR setting.
	**STEP 5. Set the Hour** The hour appears with the number flashing. Press and release the M BUTTON to obtain the desired hour. Press SET BUTTON to confirm and move to next minutes setting.
	**STEP 6. Set the Minute** The minute appears with the number flashing. Press and release the M BUTTON to obtain the desired minute. Press SET BUTTON to confirm and the meter will enter to next unit setting.
	**STEP 7. Set the Unit of Measurement** The existing unit will appear and flash. If you do not want to change the unit, press SET BUTTON to skip this step. If you want to change the unit, press and hold the M BUTTON for 3 seconds; press SET BUTTON to confirm and the meter will enter to next delete all memory setting.
	**STEP 8. Delete Memory** When the dEL symbol and the flashing memory symbol appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the SET BUTTON again to skip this step. If you want to clear ALL memory, press and hold M BUTTON for 3 seconds. The "---" image will appear on the LCD screen to indicate that all memory has been deleted.
	**STEP 9. Complete Setting** After deleting memory, the meter will display "OFF" before shut down. The meter setting is now completed.

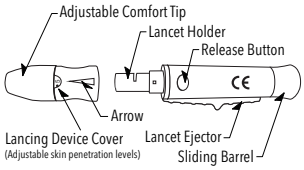
⚠ **IMPORTANT :**

1. The time, date and unit of measurement can ONLY be changed in the setting mode. Therefore, when you perform a blood glucose testing, it is not possible to change those parameters.
2. Your meter displays 7, 14, 21 and 28-day averages which you can access from the meter memory. These averages are calculated from the date of your latest result to 7, 14, 21, and 28 days before.
3. Your meter displays test results in milligram per deciliter (mg/dL) or millimoles of glucose perliter (mmol/L). Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment. Please always consult with your healthcare professionals before you reset the unit of measure.
4. While the meter is in the setting mode, if no button is pressed for 30 seconds, the meter will turn off automatically.

2. Prepare For Blood Sampling

Adjustable Lancing Device MD

Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.



Lancet MD

Protective cap

⚠Important Lancing Device and Lancets Information

1. Ⓧ Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.

⚠ **IMPORTANT :** The meter and lancing device are for single patient use. Do NOT share them with anyone including other family members ! Do NOT use on multiple patients !

Setting your Lancing Device

STEP 1:
Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.

STEP 2 :
Twist off the protective cap until it separates from the lancet.

STEP 3 :
Replace the lancing device cap and set the puncture depth to the desired number.
To select the best depth:
1-2 For delicate skin
3 For normal skin
4-5 For thick or callused skin

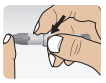
STEP 4 :
Pull back the Sliding Barrel until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.

3. Performing Blood Test

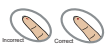
1. **Wash Your Hands and the Puncture Site :** Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.

2. **Insert Test Strip :** Remove a new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically. When the blood symbol blinking, you are ready to perform a test.

3. **Hold the lancing device firmly against the side of your finger. Press the release button to puncture the skin.** The first drop of blood usually contains tissue fluid and serum，which may affect test results and should be discarded.



4. **Obtain a Blood Sample :** Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.7 µL of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.



5. **Apply Blood Sample :** Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Then the meter begins to count down and displays the test result in 6 seconds.


Figure 1


Figure 2


Figure 3

6. **Read Your Result :**
*blood glucose value with ☺ sign
The meter will display a ☺ symbol if the result falls in the range of 70-120 mg/dL (3.9-6.7 mmol/L). See Figure 1. This default value is only for your reference, please consults your healthcare professional to find out your target blood glucose value.

*blood glucose value with ☹ sign
The meter will display a ☹ sign and following 4 warning buzzer if your test result is lower than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10 mmol/L). See Figure 2.

*blood glucose value without ☺ or ☹ sign
If your test result falls in 120-180 mg/dL (6.7 mmol/L), there will be no ☺ or ☹ sign. See Figure 3.

7. **Remove Strip to Turn Meter Off :** Your blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used strip and lancet safely in a puncture resistant container.

8. **Secure the Used Lancet:** Twist off the lancing device cap, and push the exposed tip of the lancet into its protective cap.

9. **Discard the Used Lancet :** Slide the lancet ejector forward and dispose the lancet. Discard the lancet and test strip according to your safety regulations.
* Do not reuse lancets.

4. Memory Recall

The Romed automatically stores 250 test results, letting you review them in order from the most recent to the oldest. The meter also calculates and displays 7, 14, 21 and 28-day averages. You can review the individual or average test result by entering the memory mode.

Recall the Memory

	**STEP 1. Enter the Memory Mode** PRESS M BUTTON to turn on the meter, and press M bottom again to enter memory mode.
	**STEP 2. Recalling Average Test Results** When entering the memory mode, the 7-day average will appear. If you continue to press the M BUTTON, the 14-day, 21-day, and 28-day averages will display in order.
	**STEP 3. Recalling Individual Test Results** After 28-day average, the most recent test result with date and time will be shown. Press M BUTTON once and the next most recent test result will appear. Each time you press and release the M BUTTON, the meter will recall up to your last 250 test results in order. When the memory is full, the oldest result is dropped as the newest is added.
	**STEP 4. Exit the Memory Mode** After reaching the last set of result, the meter will display "End" and turn off. Anytime in the memory mode, you can press and hold M BUTTON for 3 seconds to turn off the meter.

Deleting Individual Memory

1. When you are in the memory mode and recall the individual memory, select the test result you wish to delete and display it on the screen.
2. Press SET BUTTON. The deleting symbol "dEL" appears on the display which confirms that the selected test result has been deleted successfully.
3. The meter will return to the next individual memory recall.

SIDE B

5. Control Solution Testing

Romed control solution is available at request at the manufacturer and should be used as follows.

Romed control solutions contain a known amount of glucose that reacts with Romed test strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you can make sure that the meter and the test strips are working properly together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

Why perform a control solution test?

1. To ensure that your meter and test strip are working properly together.
2. To allow you to practice testing without using your own blood.

When should the control solution test be performed?

1. When you first get your Romed meter. Before use this system to test your blood, you can practice the procedure by using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
2. Once a week (to make sure that you continue to get accurate results)
3. When you begin using a new vial of test strips.
4. Whenever you suspect that the meter or test strips are not working properly.
5. When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
6. When test strips are exposed to extreme environmental conditions.
7. If you drop the meter.

⚠Important Control Solution Information

1. Check the expiration date on the control solution bottle. Do not use if expired.
2. Con**trol solution,** meter, and test strips should come to room temperature (68~78.8 ºF/20~26ºC) before testing.
3. Shake the bottle before use, discard the first drop of control solution after squeezing, wipes off the dispenser tip to avoid contaminations. These steps ensure you will get a good sample and an accurate result.
4. Record the discard date on the bottle when you open a new bottle of control solution.

⚠ **NOTE :** 1. There are two levels of control solution (normal and high) available to purchase. Please contact with your local distributor when required.
2. The control solution range printed on the test strip vial is for Romed Control Solution only. It is used to test meter and strip performance. It is not recommended range for your blood glucose level.

Composition:

1. D-Glucose	5. Disodium EDTA
2. Polyvinyl acetate (aqueous emulsion)	6. Food Pigment Red No.6
3. Fumed sidica	7. Antifoaming agent (Polyethylene Glycol 4000)
4. Sodium Benzoate	

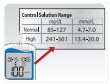
How to Perform a Control Test

1. **Insert Test Strip :** Insert a new test strip into the strip slot, the meter will activate.

2. **Mark as a Control Solution Test :** After the blood symbol(🩸) appears, press M BUTTON and "🔒" appears on the display indicating you are in the Control Solution Mode. The meter will not store your test result in the memory when you preset the test as a control solution test. If you decide not to perform a control solution test, press M BUTTON again and the "🔒" will disappear.

3. **Squeeze a drop of Control Solution :** Shake control solution bottle well. Remove the cap. Squeeze bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton swab. Squeeze a drop on a clean non-absorbent surface.

4. **Apply Control Solution :** Apply the drop to the opening of the strip absorbent channel until the confirmation window is filled. The meter begins to count down.



5. **Check if the test result is in range:** After the meter counts down from 6 to 1, the test result shows up. Compare the test result with the range printed on the test strip vial. The result should fall within the printed range.

⚠ **NOTE :** 1. DO NOT APPLY THE CONTROL SOLUTION DIRECTLY TO THE TEST STRIP! Overdosed solution may give inaccurate result.
2. Repeat test if test result falls outside the control range stated on the test strip label. If subsequent test remains to produce unacceptable result, the meter or test strip may be faulty. DO NOT use the system. Contact us or your local distributor for help.

6. Caring For Your Meter And Test Strip

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

Cleaning & Disinfecting

Please use a mild detergent and a cloth to gently wipe the exterior surfaces of the meter and the lancing device. We recommend cleaning after each use.
After finishing the cleaning process, disinfect the meter and lancing device by wiping the outer surfaces with 1:10 diluted bleach, and keep them wet for two minutes for efficacy. After disinfection, let them dry naturally at room temperature. We recommend disinfecting twice a week.
* Do not flush with water. Do not use alcohol or other solvents to clean or disinfect.
* Your meter is a precision instrument. Please handle with care.

Storage

1. Meter Storage
* Extreme Storage condition : -20 ºC ~50 ºC (-4ºF~122ºF) 90%R.H.
* Avoid dropping and strong impact.
* Avoid direct sunlight and humidity.

2. Strip Storage
* Storage condition: 4ºC~40ºC (39ºF~104ºF), and 10~85% relative humidity. Do not freeze.
* Store your test strips in their original vial only. Do not transfer to other container.
* Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
* After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
* You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.
* Use each test strip immediately after removing it from the vial.
* The strip vial contains desiccant and indicator beads at the bottom. If the indicator beads change color from blue to pink, the test strips have been exposed to moisture and should not be used.
* To ensure accurate results, do not use expired test strips or strips with indicator beads that have changed color.
* Do not bend, cut, or alter a test strip in any way.
* Keep the strip vial away from children since the cap and the test strip can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

3. Control solution storage
* Storage condition: Store the control solution tightly closed at temperatures between 4°C (39°F) and 30°C (86°F). Do not freeze.

7. System Specifications

Model Name	BGM-60
Assay Method	Electrochemical biosensor
Test Sample	Capillary Whole Blood
Test Result	Referenced to plasma glucose value
Alternative Site Testing	YES (palm, forearm, upper arm, calf, or thigh)
Sample Size	0.7 µL
Measuring Time	6 seconds
Measuring Range	20~600 mg/dL (1.1~33.3 mmol/L)
Acceptable Hematocrit Range	20~60%
Operating Condition	10°C~40°C(50°F~104°F), between 10-85% R. H.
Storage/Transportation Condition	4°C~40°C(39°F~104°F), between 10-85% R. H.
Memory Capacity	250 test results with time and date
Average Calculation	7, 14, 21, and 28 days
Power Supply	One 3-Volt Lithium Battery (battery type CR2032)
Battery Life	Approximately 1,000 tests
Automatic shut-off	In 3 minutes
Dimensions	92 x 54 x 16 mm
Weight	48g

8. About Alternative Site Testing (AST)

There are important limitations for doing AST. Please consult your healthcare professional before you perform AST.

What is AST?

Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The system allows you to test from the palm, forearm, upper arm, calf or thigh, with equivalent results to fingertip testing.

What is the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous and you will not feel as much pain as you will experience at the fingertip.

When to use AST?

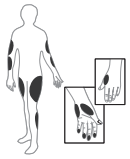
Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.

Use AST only:

1. In a pre-meal or fasting state (more than 2 hours since the last meal).
2. Two hours or more after taking insulin.
3. Two hours or more after exercise.
4. During steady state blood glucose conditions.

Do NOT use AST if:

1. You have reason to believe you have hypoglycemia or hyperglycemia.
2. Your routine glucose results are often fluctuating.
3. You are pregnant.



How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained.

Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the fingertip. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

⚠ **IMPORTANT :**
To increase the accuracy when using AST, rub the puncture site more than 20 seconds before extracting blood.

9. Display Messages And Problem-Solving Guide

The following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred.
Improper use may cause an inaccurate result without producing an error message.
In the event of a problem, refer to information under "action to take".

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check	If some parts of the display are not working. Contact your local distributor for help.
	Moving Strip	The meter is waiting for test strip to be inserted.
	Blinking Blood	The meter is ready for blood applying into test strip.
	Test result with ☺ sign	Appears when result falls in 70-120 mg/dL (3.9-6.7 mmol/L).
	Test result with ☹ sign	Appears when result is lower than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10 mmol/L).
	Test Result with No ☺ or ☹ sign	Appears when result is within 120-180 mg/dL (6.7-10 mmol/L).
	Deleting memory	Deleting is complete.

	Test result is higher than 600 mg/dL (33.3 mmol/L).	High or low blood glucose levels can indicate a possibly serious medical condition. If this is not confirmed by the way you feel, review proper testing procedure and perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.
	Test result is lower than 20 mg/dL (1.1 mmol/L).	
	Battery is dead.	Replace battery now.
	Used strip or moistened strip is inserted.	You have to: 1. Repeat test with a new test strip. 2. Contact your local distributor for help if the problem persists.
	Temperature is below the operating range.	The meter is not working. Move to an area with temperature between 10°C to 40°C (50°F ~ 104°F) and wait at least 30 minutes. Do not artificially heat or cool the meter.
	Temperature is above the operating range.	
No responses when the test strip is inserted into the meter.	Maybe: 1. Battery is dead. 2. Wrong test strip is inserted. 3. Meter is defective.	You have to: 1. Replace battery 2. Insert the test strip correctly. 3. Contact your local distributor for help if the problem persists.
No responses when blood sample is applied to the test strip.	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Contact your local distributor for help if the problem persists.

10. Performance Characteristics

Precision

Standard deviation (SD) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and coefficient of variation (CV) for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L) is ≤ 5.0 mg/dL (0.270 mmol/L) and ≤ 5.0%, respectively.

Intermediate precision

Control Solution Level (mg/dL)		Low (30~50)	Normal (96~144)	High (280~420)
Pooled	Mean (mg/dL)	44.6	100.0	351.8
	SD	3.0	2.9	8.1
	CV (%)	6.7%	2.9%	2.3%

Repeatability

Blood Glucose (mg/dL)		30~50	51~110	111~150	151~250	251~400
Pooled	Mean (mg/dL)	44.7	101.1	132	221.4	349.1
	SD	3.2	3.2	3.8	6.8	9.7
	CV (%)	7.1%	3.2%	2.9%	3.1%	2.8%

System Accuracy

For glucose concentration <100 mg/dL (5.55 mmol/L)		
Within±5 mg/dL (Within±0.28mmol/L)	Within±10 mg/dL (Within±0.56mmol/L)	Within±15 mg/dL (Within±0.83mmol/L)
109/204 (53.4%)	183/204 (89.7%)	204/204 (100%)

For glucose concentration ≥100 mg/dL (5.55 mmol/L)		
Within±5%	Within±10%	Within±15%
192/396 (48.5%)	310/396 (78.3%)	380/396 (96.0%)

For glucose concentrations between 41.5 mg/dL (2.31 mmol/L) and 525 mg/dL (29.2 mmol/L)
Within±15 mg/dL (0.83 mmol/L) or ±15%
584/600 (97.3%)

The Romed Blood Glucose Monitoring System meets the requirements for System Accuracy as stated in ISO 15197:2013.

User Performance

A study evaluating glucose values from fingertip, palm, forearm, upper arm, calf, and thigh capillary blood samples obtained by 100 lay persons showed the following results: Fingertip 100% / palm 100% / forearm 100% / upperarm 100% / calf 100% / thigh 100% within ± 15 mg/dL (± 0.83 mmol/ L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and fingertip 99.2% / palm 99.8% / forearm 98.8% / upperarm 99.4% / calf 99.4% / thigh 98.8% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL (5.55 mmol/L).