

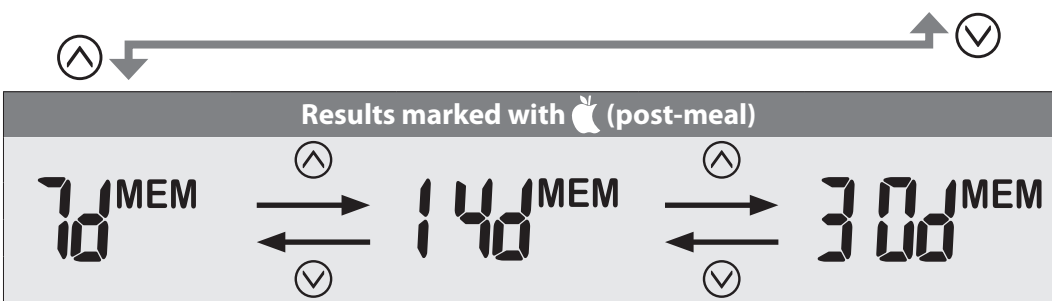
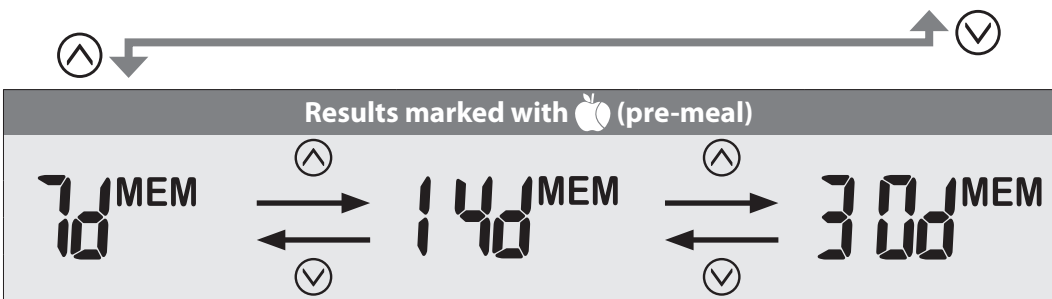
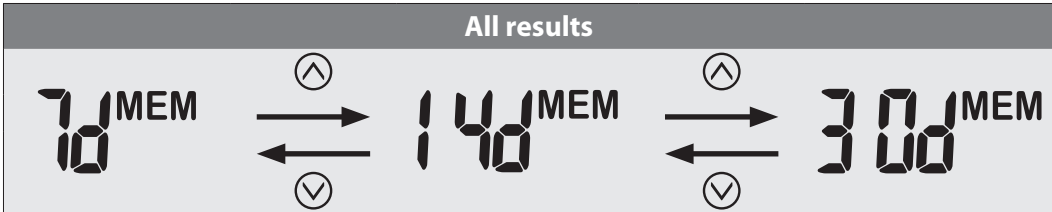
- Recalling Values from Memory**
- How to view results stored in the memory
- When the meter is off, press button to turn on the meter. The Data and Time will be shown on (At the left-upper corner. Firstly the year is shown for 1 second, and then Month-Day will be shown on in the same area.)
 - Press to view previous results. "MEM" icon will be displayed on the top center area. Initially, the "year" will be displayed on the top left corner (Fig.43). After 1 second "month-day" will then be displayed on the top left corner and "time" will be displayed on the top right corner (Fig. 44). The most recent memory results will be displayed first.
 - You can press or to scroll forwards and backwards through the results.
 - Press button to exit the stored test results or the meter will be shut off automatically after 2 minutes without any action.

- How to view the control solution test result in the memory**
- When the meter is off, press button to turn on the meter.
 - Press button again, and the latest control solution test result will be displayed (Fig. 45).
 - Press button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.

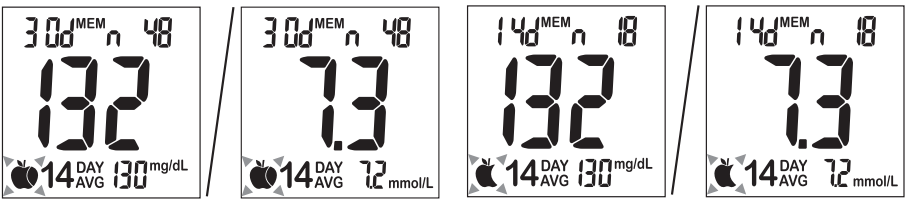
Note:

1. A result with or symbol indicates that the reading was taken out of the meter's specified operation temperature range and may not be accurate. This value is excluded from the 7/14/30 time period based glucose results average.

- View Time Periods Based Average Glucose Results**
- Press to turn the meter on, then Press button to view time periods based average glucose results.
 - 7/14/30 time periods based average glucose results marked with a no meal / pre-meal / post-meal and will be displayed on screen in sequence when is pressed (Fig. 46 ~ 48).
 - When the meter displays 7 days with no meal status assigned, press button and the meter will then change to view stored test results in memory.
 - Press button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.



(Fig. 46)



(Fig. 47)

(Fig. 48)

- The time period for glucose results average
- Meal flag (no meal / pre-meal / post-meal).
- The number used for time period based glucose results average.
- The average glucose result calculated based on time period (upper left), number of results (upper right) and meal flag (lower left).
- The average glucose result calculated from all 14 day test results.

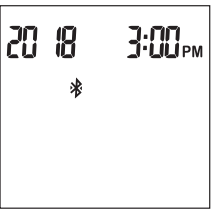
Note:

1. The consecutive 7/14/30 time period based glucose results average is calculated from the test results obtained during the last consecutive 7/14/30 day periods.

Bluetooth Data Transfer (optional)

- Initial Set-Up**
- Please visit the website at <http://www.rossmax.com> for the initial set-up instructions.
- Download and install the applicable APP onto your mobile device.
 - Turn the meter (refer to "Preparing Test Strip" section), Bluetooth and the APP of mobile device on and follow set-up and pairing instructions.
 - If the pairing is successful, once the measurement is done, the current measured reading will automatically be transferred to the APP.

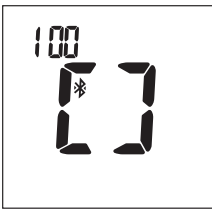
- Transfer Memory data**
- Turn Bluetooth your mobile device and applicable APP on.
 - Press to turn on the meter (Fig. 49).
 - When the meter is switched ON, hold for 4 seconds to enter Bluetooth mode. will appear and flash on the meter if the meter is not never paring with a mobile device. (Fig. 50).
 - stops blinking when the meter & mobile device is connected.
 - Press the button on APP to transfer data. The meter will display while data are being transferred (Fig. 51).



(Fig. 49)



(Fig. 50)



(Fig. 51)

PC Data Transfer (optional)

- You can use PC Link to transfer test results to your personal computer. Obtain the required software and micro USB cable to be ordered separately. Please visit the website at <http://www.rossmax.com> for proceeding the downloading and installation process.
- Follow the instructions provided with software to install the software into your personal computer.
 - Connect the interface cable to a USB port on your computer while the meter is off.
 - Connect the other end of interface cable to the data port located on the side of the meter.
 - The word "PC" will appear on the display indicates that the meter is now in the communication mode (Fig. 52).



(Fig. 52)

Cleaning and Disinfection Procedure

General Cleaning

- Switch the meter OFF.
- Use a soft cloth moistened with water or a mild detergent, gently wipe the meter surface.
- Please avoid using alcohol or organic solvents in cleaning.
- Do not immerse the meter in water when cleaning. Do not allow water or cleaning fluids into the meter, test port, and data port.

Professional Disinfection

- Applicable for people who use the blood glucose meter
- Cleaning solution and disinfecting solution: Clorox Bleach Germicidal Wipes (Clorox Professional Products Company. EPA Reg. No. 67619-12). Contact Clorox Company at 1-800-537-1415.
 - Personal Protection: Sanitize hands, and then put on gloves before removing a germicidal wipe from the canister. When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.
 - Meter: turn it off
 - Wipe: Clorox Bleach Germicidal Wipes by thoroughly wetting the exterior of the meter, allow the surface to stay wet for 1 minute then allow to air dry.
 - Disposal of Infectious Materials: Use disposable gloves. Never reuse or re-wet a disposable wipe. Dispose of according to local regulations for infectious waste disposal.
 - Please refer to the Clorox Bleach Germicidal Wipes detailed usage instructions.

Care and Storage

Please handle the meter with care. Dropping the meter may result in damage.

- Do not expose the meter, test strips, and the Control Solution to extreme conditions such as high humidity, heat, freezing cold, or dust.
- The meter should be stored at room temperature in a dry and clean area. DO NOT STORE IN DIRECT SUNLIGHT OR AREAS WITH HIGH HUMIDITY AND/OR DUST. It is advised that you store all parts of Rossmax HS200 Blood Glucose Monitoring System in the carrying bag provided.

Display Messages

Display	Description	Action
	appears when the result is HIGHER than the "HI" alert setting.	The default setting is 180mg/dL or 9.5mmol/L and it can be changed according to «Setting Up the HI/LO Alarms»
	appears when the result is LOWER than the "LO" alert setting.	The default setting is 70 mg/dL or 3.2mmol/L and it can be changed according to «Setting Up the HI/LO Alarms»
	Test result is HIGHER than 600 mg/dL (33.3 mmol/L).	Repeat the test by using a new test strip. If the same message displays again, the result is confirmed to be higher than the meter operating range. Please consult your healthcare professional immediately for further advice.
	Test result is LOWER than 20 mg/dL (1.1 mmol/L).	Repeat the test by using a new test strip. If the same message displays again, the result is confirmed to be lower than the meter operating range. Please consult your healthcare professional immediately for further advice.
	Temperature is TOO HIGH during the test procedure.	Large variation may occur between results due to high or low temperature. Move to an environment (10°C ~ 40°C or 50°F ~ 104°F) and wait for 30 minutes before re-testing.
	Temperature is TOO LOW during the test procedure.	Large variation may occur between results due to high or low temperature. Move to an environment (10°C ~ 40°C or 50°F ~ 104°F) and wait for 30 minutes before re-testing.
	The preset alarm is ringing to remind the user that it is time to perform a blood glucose test.	Please press any button to turn off the alarm or wait for the alarm to be turned off automatically in 30 seconds.
	Battery power is LOW. Meter will only provide approximately 10 more measurements.	Replace with 2 AAA batteries.

Error Messages

Display	Description	Action
	Temperature is TOO HIGH to perform a test.	Move to an environment (10°C ~ 40°C or 50°F ~ 104°F) and wait for 30 minutes before re-testing.
	Temperature is TOO LOW to perform a test.	Move to an environment (10°C ~ 40°C or 50°F ~ 104°F) and wait for 30 minutes before re-testing.
	Battery power is depleted for any further usage.	Replace with 2 AAA batteries immediately.
	This message is displayed when your meter has NOT been coded.	Please return the device to your local distributor or service center.
	An error message indicates a problem with the test strip.	Please review the instructions and try again with a new test strip. If the problem persists, please return the device to your local distributor or service center.
	An error message indicates a problem with the test strip or meter.	Please review the instructions and try again with a new test strip. If the problem persists, please return the device to your local distributor or service center.
	An error message indicates a problem with the meter.	Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly. If the problem persists, please return the device to your local distributor or service center.
	An error message indicates a problem with the test strip.	Please review the instructions and try again with a new test strip. If the problem persists, please return the device to your local distributor or service center.
	An error message indicates a problem with the meter.	Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly. If the problem persists, please return the device to your local distributor or service center.
	An error message indicates a problem with the test strip.	Please review the instructions and try again with a new test strip. If the problem persists, please return the device to your local distributor or service center.
	An error message indicates insufficient volume of blood sample for the test.	Review the instructions and try again with a new test strip, then applying a sufficient blood sample to the test strip. Please return the device to your local distributor or service center if the problem persists.

	An error message indicates a problem with the meter.	Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly. If the problem persists, please return the device to your local distributor or service center.
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Trouble Shooting

Other problems which may occur	Action
A test strip has not been inserted into the meter properly.	Review the instructions and re-insert a test strip correctly.
Defective test strip.	Replace with a new test strip.
A test strip remains in the test port for more than 2 minutes before testing.	Review the instructions and re-insert a test strip correctly.
LCD display on the meter is blank when trying to perform a test.	Please return the device to your local distributor or service center.
The meter does not function after new batteries are installed.	Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly.

Specifications

Operation Temperature	10°C ~ 40°C (50°F ~ 104°F)
Operation Humidity	10 ~ 90% RH
Hematocrit	0 ~ 70%
Test Sample	Venous and Capillary Whole Blood (fingertip, palm, forearm)
Sample Volume	0.7 µL
Measuring Unit	mg/dL or mmol/L
Measuring Range	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
Test Time	5 seconds countdown
Memory Capacity	500 most recent results
External Output	Micro USB Interface
Average	7/14/30 days average
Power supply	2 AAA batteries
Battery Life	Approximately 1000 tests
Dimension	108L x 55W x 17H mm
Weight	52 g without batteries

Note: Please refer to the Test Strip Insert for the performance of system accuracy and precision.

Electromagnetic Compatibility

This Meter meets the electromagnetic compatibility requirements as per EN 61326-1 and EN 61326-2-6.

Caution: Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.

Tolerance summary of interference substance	
Interference substance	Highest tested concentration with no significant interference
Acetaminophen	4.25 mg/dL
Ascorbate(Ascorbic acid)	3 mg/dL
Bilirubin	25 mg/dL
Cholesterol	1200 mg/dL
Creatinine	10 mg/dL
Dopamine	2 mg/dL
EDTA	200 mg/dL
Galactose	500 mg/dL
Genistic acid	2.5 mg/dL
Glutathione	3.07 mg/dL
Haemoglobin-HUMAN	3000 mg/dL
Heparin	5 IU/ml
Hydrogenated starch hydrolysates (HSH)	0.09 mg/dL
Ibuprofen	50 mg/dL
Icodextrin	750 mg/dL
Isomalt	0.09 mg/dL
Lactitol	0.09 mg/dL
L-DOPA(L-3-4 dihydroxyphenylalanine)	0.5 mg/dL
Maltose	2575 mg/dL
Maltitol	0.09 mg/dL
Mannitol	0.09 mg/dL
Methylodopa	2.5 mg/dL
Pralidoxime iodide (PAM)	5 mg/dL
Salicylate	50 mg/dL
Sodium Carbonate	37.5 mEq/L
Sorbitol	0.09 mg/dL
Tolbutamide	100 mg/dL
Tolazamide	6 mg/dL
Triglycerides	1525 mg/dL
Uric acid	8 mg/dL
Xylose	5 mg/dL
Xylitol	0.09 mg/dL

Warning Xylose

Xylose would result in the overestimation of blood glucose reading if the blood sample containing xylose with the concentration over 5 mg/dL. Do not use this system during or shortly after receiving xylose absorption therapy since xylose may case inaccurate blood glucose results.

Meter Storage

- Transport and store at temperature -20°C ~ 50°C (-4°F ~ 122°F), Less than 90% RH
- Precision instrument, do not crash when being transported.

Explanations of Symbols

	Authorised Representative in the European Community		Manufacturer
	Do not use if package is damaged		In vitro diagnostic medical device
	Temperature limitation		Consult instructions for use
	Batch code		Sufficient for
	Use by		Catalogue number
	Keep dry		Keep away from sunlight
	Do not reuse		Control
	Serial Number		Caution



Blood Glucose Monitoring System

Instruction Manual

www.rossmax.com

Limitations of the Procedure

Caution:

- Rossmax HS200 Blood Glucose Monitoring System is designed for in vitro diagnostic use only and is not intended to test on neonate.
- Any change or administer of medication based on the Rossmax HS200 blood glucose test results without the consent advice of a physician or healthcare professional is not recommended.
- The Rossmax HS200 Blood Glucose Test Strip are designed for use with fresh venous whole blood or capillary whole blood samples obtained from the fingertip, palm and forearm. DO NOT use samples other than venous whole blood or capillary whole blood.
- False results may occur when performing the test while severely dehydrated, severely hypotensive, in shock or in a hyperglycemic-hypersmolar state. If you believe you are suffering from any of the above symptoms, consult a healthcare professional immediately.
- Please refer to Rossmax HS200 Blood Glucose Test Strip Package Insert to access further information on strip limitations.

Service and Warranty

IMPORTANT

- The Rossmax HS200 Blood Glucose Meter, Rossmax HS200 Blood Glucose Test Strip and Control Solution are in conformity with the IVDD 98/79/EC.
- Rossmax HS200 Blood Glucose Monitoring System manufacturer warranty is valid only when used properly within the guidelines of this User Manual provided.
- The Lancing device and Lancets are in conformity with the MDD 93/42/EEC.

Manufacturer Warranty

This instrument is covered by a 3 year guarantee from the date of purchase, batteries and accessories are not included. The guarantee is valid only on presentation of the guarantee card completed by the dealer confirming date of purchase or the receipt. Opening or altering the instrument invalidates the guarantee. The guarantee does not cover damage, accidents or non-compliance with the instruction manual. Please contact your local seller/dealer or www.rossmax.com.

Customer Name: _____

Address: _____

Telephone: _____

E-mail address: _____

Product Information: _____

Date of purchase: _____

Store where purchased: _____

✉ Rossmax Swiss GmbH, 9435 Heerbrugg, Switzerland, www.rossmax.com

Manufacturer of Blood Glucose Meter, Test Strip and Control Solution

✎ Tyson Bioresearch, Inc.

5F., No. 16, 18, 20, 22, Kedong 3rd Rd., Zhunan Township, Miaoli County 35053, Taiwan

✉ Medical Device Safety Service GmbH Schiffgraben 41, D-30175 Hannover, Germany

Manufacturer of Lancet and Lancing Device

✎ Shandong Lianfa Medical Plastic Products Co., Ltd.

No.1 Shuangshan Sanjian Road 250200 Zhangqiu City, Jinan, Shandong PEOPLE'S REPUBLIC OF CHINA

✉ Shanghai International Holding Corp. GmbH (Europe) Eistraße 80, 20537 Hamburg, GERMANY

✎ MEDIFUN CORPORATION (Lancing Device Only)

No.8, Shuyi Rd., South Dist., Taichung City, 40241, Taiwan (R.O.C.)

✉ MDSS GmbH Schiffgrobren 41,30175 Hannover, Germany

Introduction

Thank you for choosing Rossmax HS200 Blood Glucose Monitoring System to monitor your blood glucose level. It is designed to be accurate, easy to use, and quick in response time. This User Manual will provide you with all the information you need to operate and maintain Rossmax HS200 Blood Glucose Monitoring System. Please read carefully and completely before use.

Rossmax HS200 Blood Glucose Meter can be used with:
Rossmax HS200 Blood Glucose Test Strip

Rossmax HS200 Blood Glucose Monitoring System is for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip, palm, and forearm; or venous whole blood. It is Only for use outside the body (For in vitro diagnostic use) and intended for self-testing at homes and under professional settings to monitor blood glucose levels.

Test Principle

On each test strip there is a target area containing reaction chemicals. When blood is applied to this area, a chemical reaction takes place, then a transient electrical current is formed. The blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is showed on the display. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3mmol/L). The Rossmax HS200 Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

- ⚠ Caution**
- **Do not use the device to diagnose diabetes; it is intended for regular monitoring only.**
 - **Consult your physician with regard to insulin doses.**

Important Safety Instructions

For Home Use

- All parts of Rossmax HS200 Blood Glucose Monitoring System should be considered potentially infectious and are capable of transmitting blood-borne pathogens. To assure that you are not placing yourself at risk, always remember:
- The meter and lancing device is for single person use. Do NOT share them with anyone including other family members! Do not use on multiple people!
 - All parts of the kit are considered to be bio-hazardous and can potentially transmit infectious diseases even after cleaning and disinfection have been performed.

Reference:

- “FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
- “CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)
http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html
- “CDC: Infection Prevention during Blood Glucose Monitoring and Insulin Administration” (2010)
http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

For Professional Use

- Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007”, http://www.cdc.gov/hicp/ac/2007/p/2007isolationprecautions.html.
- The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer’s disinfection procedures are followed.
- Only auto-disabling, single use lancing devices may be used with this device.
- Cleaning Solution and Disinfecting Solution: Clorox Bleach Germicidal Wipes (Clorox Professional Products Company, EPA Reg. No. 67619-12). Contact Clorox Company at 1-800-537-1415.

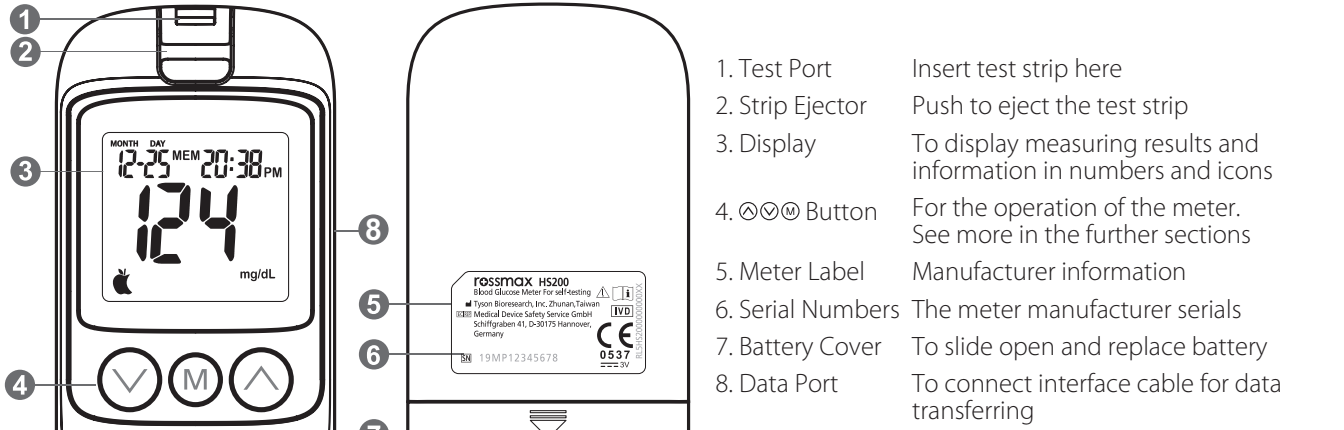
About Rossmax HS200 Blood Glucose Monitoring System

The complete kit contains:

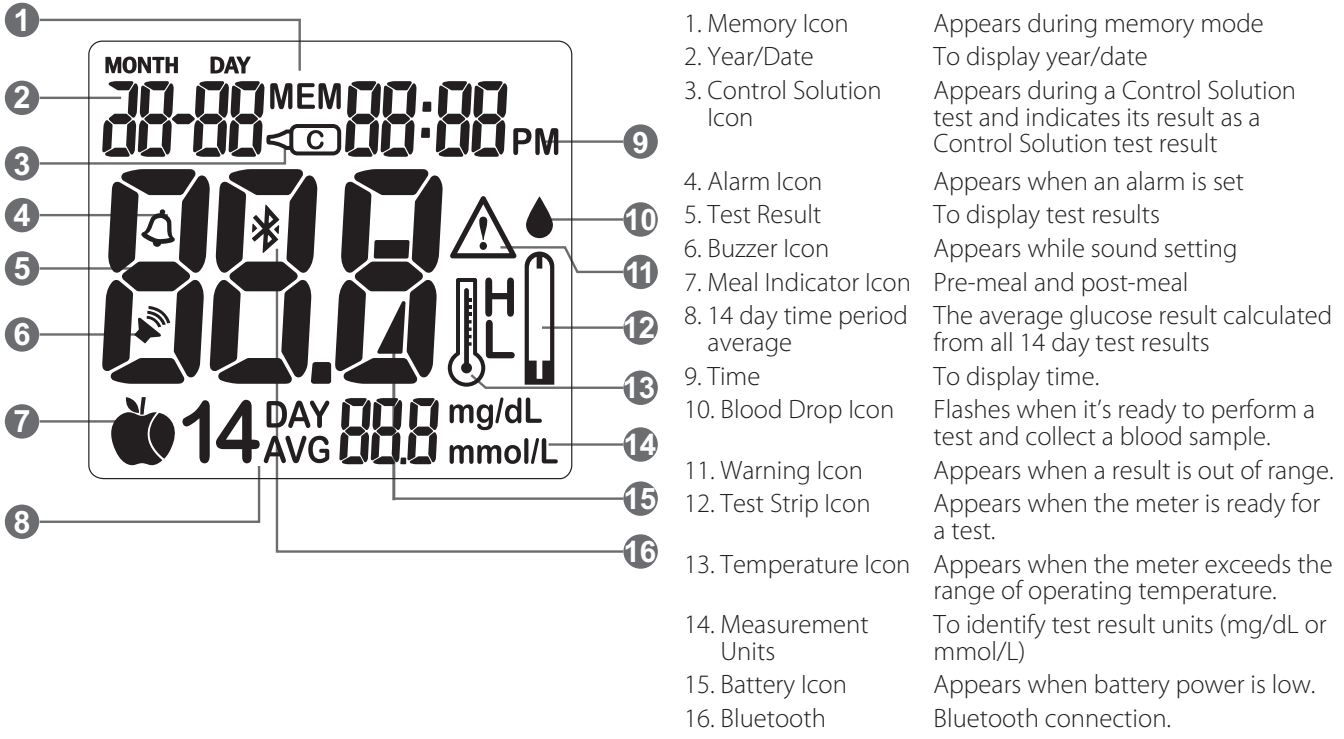
- One Rossmax HS200 Blood Glucose Meter
- One Rossmax HS200 Blood Glucose Test Strip vial
- One bottle of Rossmax HS200 Control Solution
- One lancing device
- Lancets
- One Rossmax HS200 Blood Glucose Monitoring System User Manual
- One Rossmax HS200 Blood Glucose Monitoring System Quick Reference Guide
- One Rossmax HS200 Blood Glucose Test Strip Package Insert
- One Rossmax HS200 Control Solution Package Insert
- One Lancing Device Package Insert
- One Log Book
- One carrying bag

The actual composition is marked on the kit box. Some of items may not be included.

About Rossmax HS200 Blood Glucose Meter



About Rossmax HS200 Blood Glucose Meter Display



About Rossmax HS200 Blood Glucose Test Strip

Rossmax HS200 Blood Glucose Test Strip is for blood glucose tests in conjunction with Rossmax HS200 Blood Glucose Meter. Each strip can be used ONCE ONLY!

A test strip consists of the following parts:

1. Target Area: Where a blood drop or control solution is touched.
2. Confirmation Window: To confirm if sufficient blood drop or control solution has been applied to Target Area.
3. Contact Bar: The end of the test strip is to be inserted into the test port (top side facing up).

Checking the Unit of Measurement

1. Check if your meter displays the **Unit of Measurement** you are accustomed.
2. You can find the **Unit of Measurement** that your meter displays on the meter label.
3. If you do not know which is the right **Unit** for you, ask your healthcare professional.

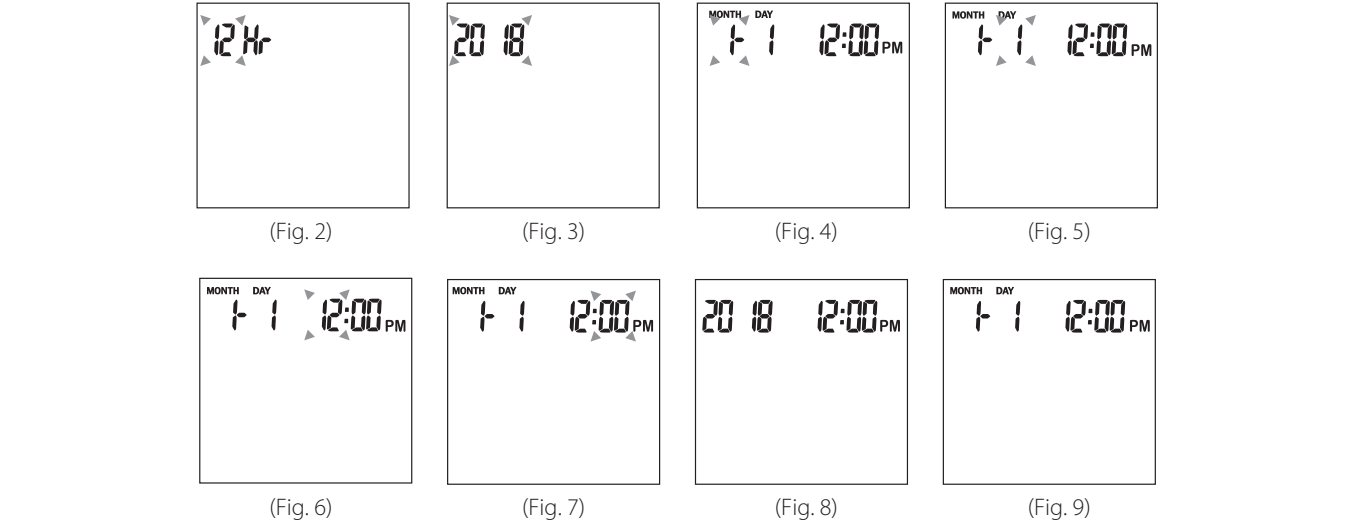
Setting Up Rossmax HS200 Blood Glucose Meter

Installing/Replacing Batteries (Fig.1)

1. From the back of the meter, gently slide and remove the battery cover.
2. Install batteries with the + and – ends matching indication marks on the battery compartment. The meter requires 2 AAA batteries.
3. Slide battery cover back into place.

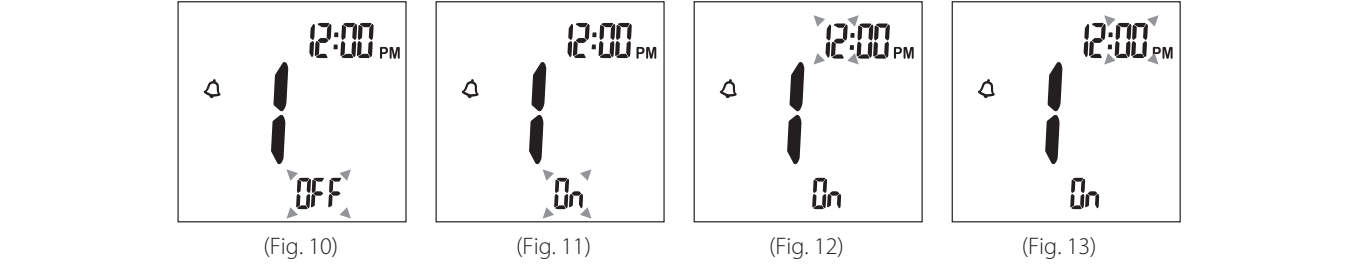
Setting Date/Time

1. When the meter is off, press and hold ⊕ button for 4 seconds to enter this setting mode.
2. Press ⊙ or ⊗ to select “24hr” or “12hr”. Press ⊙ to confirm (Fig.2).
3. The numbers of “year” will appear and flash. Press ⊙ or ⊗ to adjust and Press ⊙ to confirm (Fig.3).
4. The number of “month” will appear and flash. Press ⊙ or ⊗ to adjust and press ⊙ to confirm (Fig.4).
5. The numbers of “day ” will appear and flash. Press ⊙ or ⊗ to adjust and press ⊙ to confirm (Fig.5).
6. The numbers of “hour” will appear and flash. Press ⊙ or ⊗ to adjust and press ⊙ to confirm (Fig.6).
7. The numbers of “minute” will appear and flash. Press ⊙ or ⊗ to adjust and press ⊙ to confirm (Fig.7). The set date and time will now display on the LCD screen (Fig.8, Fig.9).
8. Press ⊙ to turn off the meter. The meter date/time setting is complete.



Setting Up Reminder Alarms

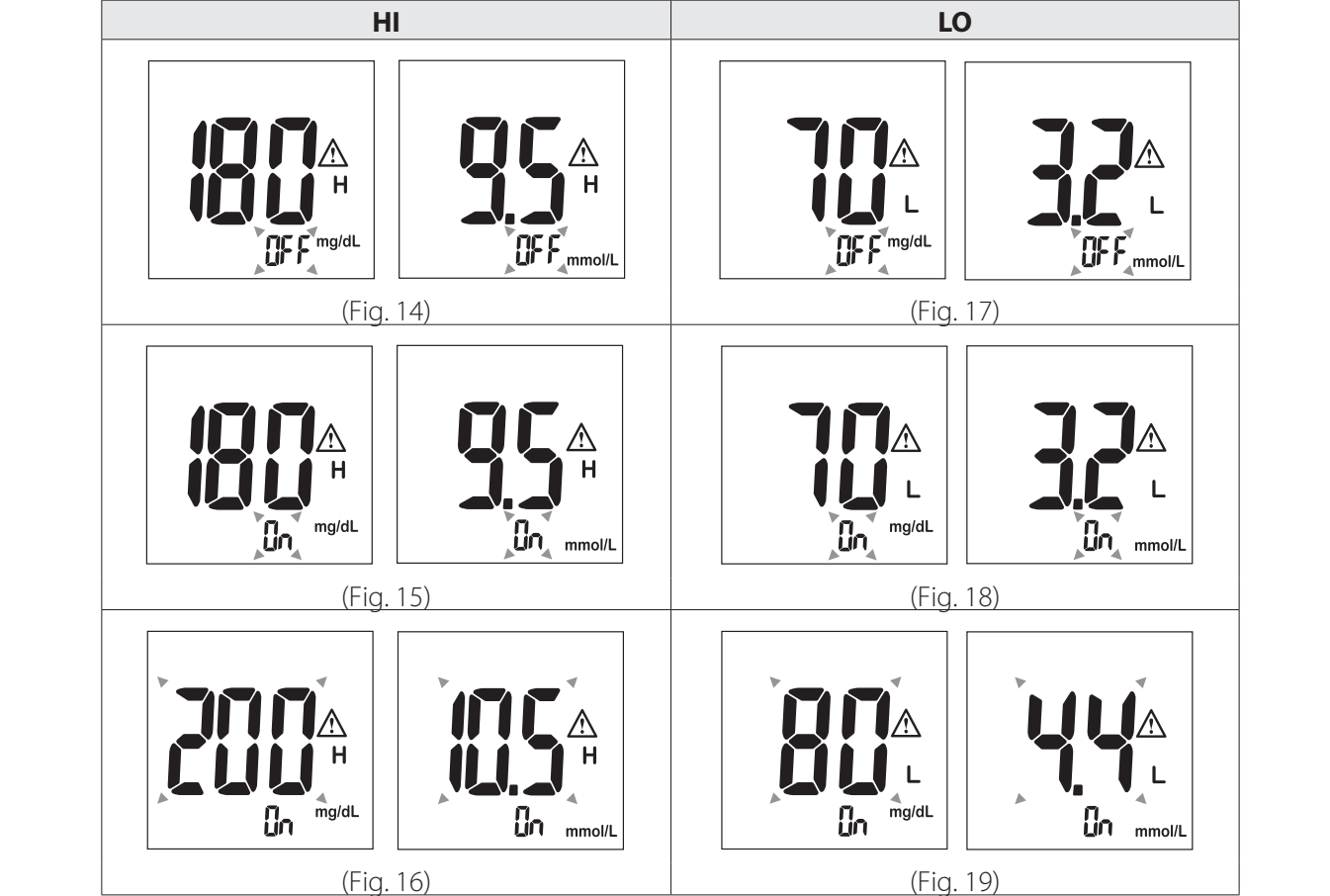
- Rossmax HS200 Blood Glucose Meter provides 4 reminder alarms. All reminder alarms are OFF as default. Please follow these steps to setup reminder alarms.
1. When the meter is OFF, press and hold ⊕ button for 4 seconds or longer to enter setting.
 2. The first reminder alarm will appear on the display (Fig.10).
 3. Press ⊙ or ⊗ to select “ON” or “OFF”. If “OFF” is chosen and ⊕ pressed, the meter will proceed to the next reminder alarm setting. If “ON” is chosen (Fig.11) and ⊕ pressed, the number of “hour” will start flashing (Fig.12).
 4. Press ⊙ or ⊗ to adjust and press ⊙ to confirm.
 5. The numbers of “minutes” will flash (Fig.13). Press ⊙ or ⊗ to adjust and press ⊙ to confirm. The meter will go to the next reminder alarm setting.
 6. Repeat steps 3 to 5 to set the rest of reminder alarms.



Setting Up HI/LO Alarms

Rossmax HS200 Blood Glucose Meter provides HI/LO alarm.

1. After completing the reminder alarm setting, press ⊙ to enter the HI alarm setting.
2. Press ⊙ or ⊗ to set “ON”, press ⊙ to confirm. If “OFF” is chosen, the meter will skip this setting (Fig. 14, 15).
3. To change the alarm setting, press ⊙ or ⊗ until you reach your desired HI setting and then press ⊙ to confirm (Fig.16). The HI alarm value range is 100 ~ 400mg/dL (5.5 ~ 22.0mmol/L) and the default value is 180mg/dL or 9.5mmol/L.
4. Continue to the LO alarm setting (Fig.17), the LO alarm value range is 40 ~ 90mg/dL (2.0 ~ 5.0mmol/L) and the default value is 70mg/dL or 3.2mmol/L. Repeat Step 2 and 3 (Fig.18, 19) to set up your desired LO alarm setting, press ⊙ to confirm and the meter will be turned off.



Important Information

Before Testing

- Always keep test strips in the original vial. Tightly close the vial cap immediately after removing a test strip.
- Use each strip immediately after removing it from the vial. Each test strip should be used ONCE ONLY.
- Do not use test strips or Control Solution beyond the expiration date printed on the package since this may cause inaccurate results.
- Store your test strips and the meter in a cool, dry place between 4°C and 30°C (39°F and 86°F). Temperatures beyond this range, as well as humidity, can damage test strips and lead to inaccurate results.
- Any change of medications based on the Rossmax HS200 Blood Glucose Monitoring System results without advices of a doctor is NOT RECOMMENDED.
- The lancing device is intended only for single user and should NOT be shared.
- Only Rossmax HS200 Blood Glucose Test Strips and Control Solution can be used with the Rossmax HS200 Blood Glucose Meter.
- For accurate results, testing must be done within the operating temperature range (10 - 40°C/ 50 - 104°F). If the meter is moved to an area appropriate conditions from where is out of operating temperature range, place the meter for 30 minutes before conducting the testing.

Preparing Test Strip

Before testing, you need the following items:

- Rossmax HS200 Blood Glucose Meter
- Rossmax HS200 Blood Glucose Test Strip
- Lancing device and sterile lancet

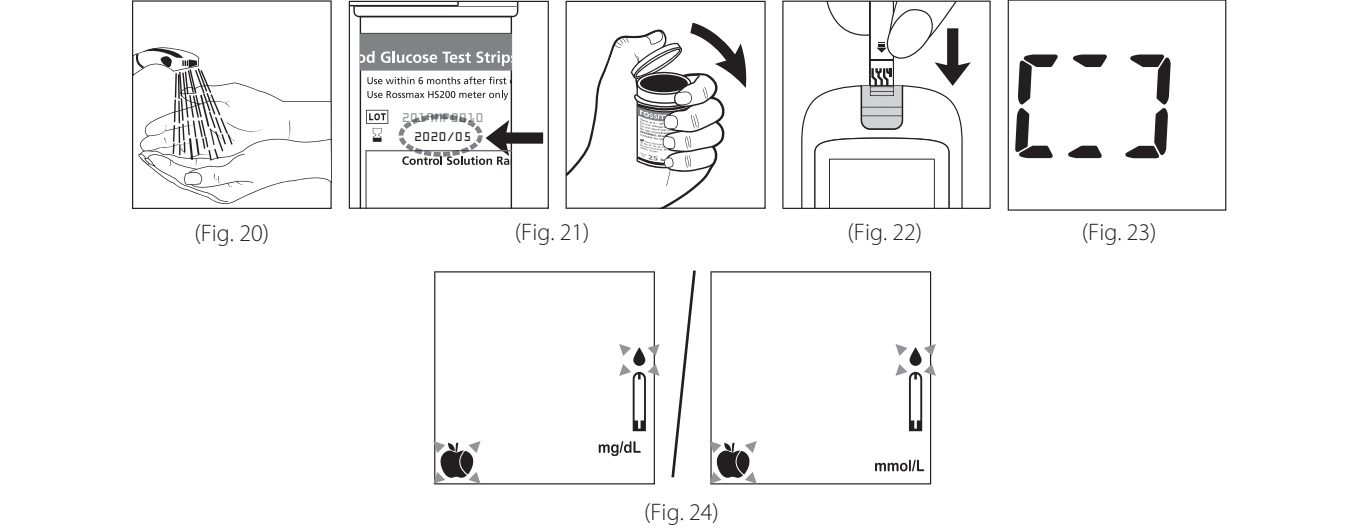
Preparing the Test Strip

1. Wash hands using soap and warm water. Rinse and dry thoroughly (Fig. 20).
2. Please remove protective wrap completely before opening the vial.
3. Check the use by date on the test strip vial; use only test strips which are within the use by date. Take a test strip from the vial and re-cap the vial immediately (Fig. 21).
4. Insert the test strip, top side facing up into the test port. The meter will automatically turn on (Fig. 22).
5. System checking will appear (Fig. 23).
6. A beep will sound, you can press ⊙ or ⊗ to select the meal indicator for marking the test as pre-meal test ●, post-meal test ◐, or no marker (default) (Fig. 24).

Note: Check if your meter displays the unit of measurement you are accustomed.

7. A blood sample can now be obtained (refer to next section).

Note: The meter will shut off automatically after 2 minutes without any action.



Preparing the Lancing Device and Obtaining a Blood Sample

1. Unscrew the lancing device cap (Fig.25).
2. Place a lancet into the lancing device (Fig.26).
3. Twist and pull to remove the protective lancet cap to expose the sterile needle, save the cap for later use (Fig. 27).
4. Screw the lancing device cap back on. Select the skin penetration depth preferred (Fig. 28).
5. Pull the barrel back until you hear a ‘click’ sound (Fig. 29).
6. Place the lancing device softly against the finger, palm, or forearm, and press the release button to obtain a blood sample (Fig. 30).

To unload the lancing device

1. After sampling, remove the cap containing the used lancet carefully.
 2. Push the exposed tip of the lancet into its Protective Cap (Fig.31). Slide the Lancet Ejector forward and disposing the used lancet in an approved container.
- For further instructions please see the insert provided with the lancing device.

CAUTION:

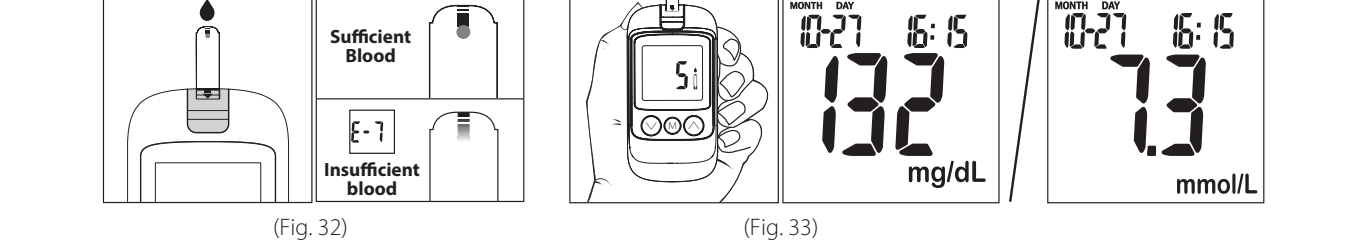
To reduce chances of infection:

- **Always use a new and sterile lancet. Lancets are for single usage only.**
- **Wash hands thoroughly with soap and water before and after handling the meter, lancing device, and test strips.**
- **Please refer to “Cleaning and Disinfection Procedure” section for detail instructions of meter maintenance.**

Applying a Blood Sample to the Test Strip to perform a test

SAMPLE MAY BE OBTAINED FROM FINGER, PALM OR FOREARM

1. After obtaining a blood sample, discard the first drop to prevent contamination. Introduce the tip of the test strip to the drop of blood. Blood sample will be automatically drawn into the test strip (Fig. 32).
2. Hold the tip of the test strip touching the blood drop until the meter beeps.
3. As soon as the blood has completely filled the confirmation window of the test strip, the meter will start a countdown. The test result will appear on the display after 5 seconds and will be automatically stored into the meter memory (Fig. 33).



4. After the test result appears and if there is no further test, the meter will automatically turn off after 2 minutes. If applying a blood sample of reduced volume, the error code (E-7) will appear on the display (Error code is described clearly in “Error Messages” section).

Test Results

1. The Rossmax HS200 Blood Glucose Meter displays the test result.
2. The LCD of the meter shows the measuring result, the date and the time (Fig. 34).

Normal Glucose Values

- The glycemic recommendations for nonpregnant adults with diabetes:
- Preprandial capillary plasma glucose: 80 ~ 130 mg/dL (4.4 ~ 7.2 mmol/L).
- Peak postprandial capillary plasma glucose: 180 mg/dL (10.0 mmol/L).
- Diabetic patients may have blood glucose values that are moderately elevated.

Ejecting the used Test Strip and Disposing of the Used Lancet

Ejecting the used Test Strip

1. After completing the test, push the strip ejector (Fig. 35) or use a tissue paper to remove the test strip.
- To unload the lancing device**
1. After sampling, carefully remove the cap containing the used lancet (Fig. 36).
2. Push the exposed tip of the lancet into its Protective Cap (Fig. 36). Slide the Lancet Ejector forward and dispose the used lancet in an appropriate container .

For further instructions please see the insert provided with the lancing device.

Warning:

- **DO NOT point the test strip at anyone when ejecting.**
- **Used lancets and test strips are considered bio-hazardous. Dispose of used lancets and test strips in a clinical waste container.**

HI and LO Readings

Rossmax HS200 Blood Glucose Meter is designed to display test results between 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L). If a “HI” (Fig. 37) or a “LO” (Fig. 38) message appears on the display, it indicates that the meter has detected a blood glucose level is higher than 600 mg/dL (33.3 mmol/L) or lower than 20 mg/dL (1.1 mmol/L). It is suggested the testing procedure should be reviewed and the test should be repeated using a new test strip to confirm the result again.

Available Alternative Sites Testing

Palm and Forearm

Rossmax HS200 Blood Glucose Monitoring System provides you alternative sites testing (AST). This system provides you to test on the palm and the forearm with the equivalent results to fingertip testing.

Caution:

Physiological differences in the circulation between the finger and other test sites like the forearm and palm may result in differences in blood glucose measurements from the other test sites and your fingertips. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the forearm and other alternative sites. Rub the alternative test sites about 20 seconds before lancing. If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingertips.

Talk to your doctor to see if alternative site testing is right for you. With a little bit of education, you can give your fingertips a rest and maybe test more often than you do now. For people with diabetes, more frequent testing is a good thing. Just remember: any time you want to be sure of an accurate, up-to-date blood glucose reading, test on your fingertip. We strongly recommend you do.

AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Control Solution (optional)

The Control Solution is to ensure that Rossmax HS200 Blood Glucose Meter is working properly and the user is performing a test correctly, please contact your local distributor or service center on where to obtain control solution.

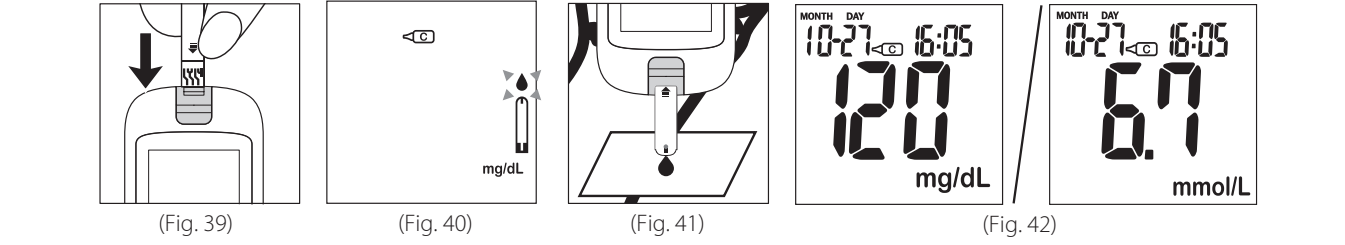
When to Perform a Control Solution Test

1. You get your meter for the first time before testing your blood test.
2. You open a new vial of test strips.
3. You want to check the meter and strips.
4. You suspect that the meter or test strips are not working properly.
5. Your blood glucose test results are not consistent with how you feel.
6. You think your test result does not accurate.
7. You dropped your meter.
8. Whenever your healthcare professional recommends it.

Note: For more information regarding the Control Solution, please read the Control Solution package insert.

Performing a Control Solution Test

1. Prepare a vial of Rossmax HS200 Blood Glucose Test Strip within the use by date and a Rossmax HS200 Blood Glucose Meter.
2. Be sure of the Rossmax HS200 Blood Glucose Meter, Rossmax HS200 Blood Glucose Test Strip and Control Solution are at room temperature between 15°C ~ 35°C (59°F ~ 95°F) before testing.
3. Insert a Rossmax HS200 Blood Glucose Test Strip into the test port. The meter will be automatically turned ON (Fig. 39).
4. When test strip is inserted, a beep will sound if the buzzer is turned on and the system checking will appear followed by a flashing “●” icon (Fig. 40).
5. Press and hold ⊕ button for 2 seconds to change to the Control Solution test mode. “◐” will appear on the display. If ⊕ button is pressed again for 2 seconds, the meter will switch back to the normal testing mode.
6. Shake the Control Solution gently. Discard the first drop of the Control Solution and squeeze a small drop on a clean nonabsorbent surface such as a clean piece of wax paper (Fig. 41). Do not apply the Control Solution to the test strip directly from the bottle, as contamination may occur.
7. Introduce the tip of the test strip to the droplet of the Control Solution. The Control Solution is automatically drawn into the strip. Hold until the meter beeps. The meter will now start to count down and the Control Solution test result will appear on the LCD screen (Fig. 42).



Caution: If your room temperature is not between 15°C ~ 35°C (59°F ~ 95°F), the Control Solution Test Result will incorrect.

Control Solution Results

The Rossmax HS200 Blood Glucose Meter is functioning correctly only if the Control Solution test result is within the specified range printed on the test strip vial. If the test result is out of range, please repeat the test.

Out of range result may be caused by:

- Incorrect steps taken in performing the test.
- The Control Solution may be expired or contaminated or has been opened over 3 months.
- The Control Solution temperature is not within 15°C(59°F)- 35°C(95°F) prior to testing.
- Expired or contaminated test strips.
- Meter malfunction.

Note:

- **The result under Control Solution test mode will not be included in time period based glucose results average calculation.**
- **DO NOT use Rossmax HS200 Blood Glucose Meter if the problem persists. Please return the device to your local distributor or service center.**