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INTRODUCTION

The MediSure Blood Glucose Monitoring System has been Licensed by Health Canada for Multi Patient Use . It is intended for use by health care professionals on multiple patients. It is certified as safe to use for over 18,000 tests and in-between cleaning protocols.

The compact and portable **MediSure** Blood Glucose Meter is easy to use, and displays test results in only 6 seconds. In addition, the meter automatically stores up to 960 test results with respective dates and times, which allows you to monitor your Diabetes program efficiently.

Before testing, please read this User's Guide thoroughly. It contains all the information you need regarding the **MediSure** Blood Glucose Monitoring System. If you have product related questions please call our Customer Assistance line at 1-855-634-7873 from 8:00 AM to 6:00 PM, Eastern Standard Time Monday through Friday. For customer assistance outside these times, please leave a message with your full contact information including a contact phone number. In case of a medical emergency, please contact your health care provider.

TESTING PRINCIPLE

The **MediSure** Blood Glucose Monitoring System is designed to provide an easy, accurate method for determining capillary blood glucose values. This analysis is based on amperometric technology using glucose oxidase that is specific for the blood glucose measurement.

INDICATIONS FOR USE

The **MediSure** Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. It is to be used as an aid in monitoring the effectiveness of a Diabetes control program.

It is not intended for the diagnosis of, or screening for diabetes mellitus, and is not intended for use on neonates.

Because this is a multi-user device, the disinfection protocol found on pages 25-28 must be followed after each use.

IMPORTANT SAFETY INSTRUCTIONS

Users must 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 blood-borne pathogens between patients and healthcare professionals.

- The **MediSure**[®] 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.

For more information, refer to *“Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings”*,

<https://www.canada.ca/en/public-health/services/publications/diseases-conditions/routine-practices-precautions-healthcare-associated-infections.html>

CONTENTS AND SPECIFICATIONS

Meter Kit Contents

- **MediSure** Blood Glucose Meter
- 3-Volt Lithium Battery (CR2032)
- User Guide
- Quick Start Guide
- Carrying Case
- Warranty Card

Meter Specifications

Storage Conditions	Temperature: -20°~+50°C Humidity RH \leq 80%
Memory Capacity	960 test results with respective dates and times
Measurement Unit	mmol/L
Display	LCD display
Reaction Time	6 Seconds or less
Meter Dimensions	54×93×16 Millimeters
Meter Weight	53 Grams (with battery)
Measuring Range	1.1~41.7 mmol/L
Power Supply	One 3 Volt lithium battery (Model CR2032)
Battery Lifetime	Over 1,000 tests

Test Strip Specifications

Strip Size	35 × 6 × 0.6 Millimeters
Storage Conditions	Temperature: 2°~30°C Humidity: RH ≤ 80%
Blood Volume	0.6 μL
Expiration of Test Strips	See printed expiry on the side of test strip box or vial

System Operating Conditions

Test Strips	Use only Medi+Sure Blood Glucose Test Strips
Operating Conditions	Temperature: 10°~40° C Humidity: RH ≤ 80%
Sample Type	Capillary whole blood in finger
Hematocrit of Tested Blood	25%~60%
Altitude Limit	To be used no higher than 10183 feet above sea level

The meter is calibrated to capillary whole blood equivalent results

ABOUT THE MediSure SYSTEM

LCD Display

Blood Glucose Test Results & Messages

Left Arrow Button

*Show Time
Alarm Set*

Main Button

*Power on
Memory Recall*

Settings Button

*Set Date & Time
Power Off*

Right Arrow Button

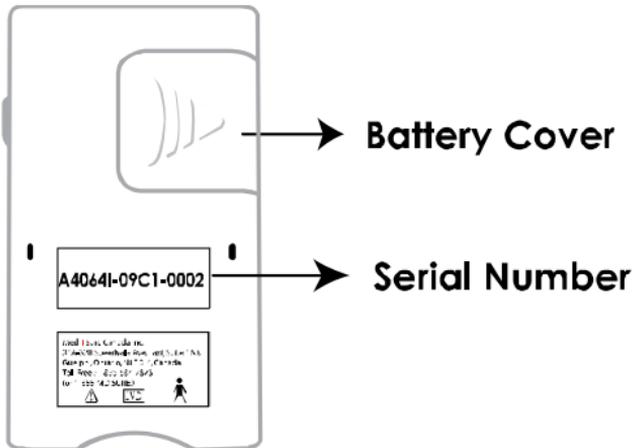
Temperature

Strip Port

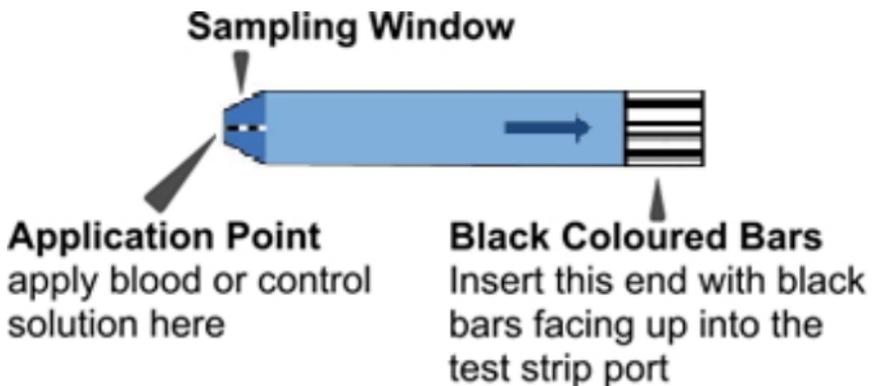
*Insert Test
Strip Blue Side up*



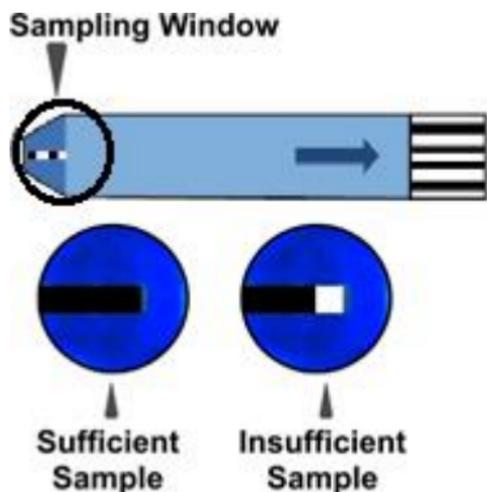
Meter Back



MediSure Blood Glucose Test Strip



How to determine whether blood sample is sufficient



NOTE:

If the sample is sufficient, the sampling window on the test strip should be full with no white space showing.

HOW YOUR SYSTEM WORKS

Installing or Replacing the Battery

Your **MediSure** Blood Glucose Monitoring System is packed with one 3-volt lithium coin battery that needs to be installed before testing. The battery will last for approximately 1,000 tests. Always keep spare batteries on hand.



When the battery symbol appears on the display, it means your battery is low. Although the meter will still provide accurate results, the battery should be replaced as soon as possible. After the battery is replaced, reset the date, and time.

1. Open the battery cover by pressing on it and sliding it in the direction of the arrows on the battery cover.
2. If replacing battery, remove the old battery.
3. Insert a new battery firmly with the positive (+) side up. The LCD will display "Set."
4. Reset the date, time.



Powering the Meter On and Off

Powering the Meter On

Press the  button to power on the meter.

The Meter will power on, and prompt you to insert a test strip.

The meter will stay on for 1 minute.

Or

Insert a Test Strip into the meter.

The Meter will power on, and prompt you to take blood sample.

The meter will stay on for 3 minutes.

Powering the Meter Off

Press the  button.

The Meter will display “OFF” then power off.



Setting the Date & Time

Press and hold the  button for 3+ seconds.

The year flashes on the screen.



Press the “>” or “<” buttons until the correct year is displayed



Press the  button again, the month flashes on the LCD screen

Press the “>” or “<” buttons until the correct month is displayed.



Press the  button.
The day flashes.

Press the “>”  or “<”  buttons until
the correct day is displayed.



Press the  button. The hour
flashes.

Press the “>”  or “<”  buttons
until the correct hour is displayed.



Press the  button. The
minutes flash.

Press the “>”  or “<”  buttons
until the correct minutes are
displayed.



Press the  button.

“**Set**” will display.

The meter beeps and shuts off.



All date and time settings will be saved.

NOTE:

- To quickly adjust any function, keep pressing the “>” or “<” buttons until the one you want appears.
- At any point, if you want to shut the meter off, press the  button for about 3 seconds and all setting will automatically be saved.

Alarm Settings

1. Press and hold the “<”  button for 3+ seconds.
2. You will hear a beep and the meter will power on. The LCD display lights up
3. Press the  button to activate the alarm and alarm symbol  flashes on the screen. You can set the alarm on or off by pressing the “>”  or “<”  buttons.
4. Press the  button again, the hour flashes on the LCD screen.
5. Press the “>”  or “<”  buttons button until the correct hour is displayed.
6. Press the  button. The minute flashes.
7. Press the “<”  or “>”  buttons until the correct minutes is displayed.
8. Press the  button, the meter beeps. The LCD display shows “ok”.
9. Pressing the  button, you can set AL 2 through 4.
10. Press the  button at least 3 seconds, the meter beeps. After “SAVE” displays on the screen, the meter shuts off. All settings will be saved.

Reviewing Results in Memory

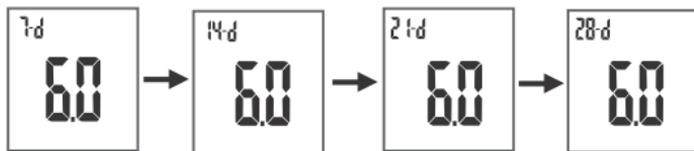
The **MediSure** Blood Glucose Meter automatically stores up to 960 test results with date and time. You can review test results from the newest to the oldest. Results stored in memory will not be lost when you replace the battery.

Viewing individual test results

1. Press the  button to turn on the meter.
2. When the test strip symbol flashes, press the  button again.
3. Your last test results in memory will be displayed, the latest test result will be shown for one minute. The number in memory (e.g. 001) will flash on top with the result. The date and time will be displayed at the top of the screen.
4. To quickly recall a certain test result, keep press the “<”  or “>”  buttons until the one you want appears.
5. If there are no tests recorded in the meter, “**0 MEM**” is displayed.
6. At any point, if you wish to shut the meter off, press the  button.

Viewing 7, 14, 21 and 28 Day Averages

1. While viewing individual test results, Press the  button again.
2. The 7 day average result will be shown on the screen for 1 minute.



3. Press the “>”  button again, the 14 day average result will be shown on the screen for 1 minute.
4. Press the “>”  button again, the 21 day average result will be shown on the screen for 1 minute.
5. Press the “>”  button again, the 28 day average result will be shown on the screen in 1 minute.
6. At any point, if you wish to shut the meter off, press the  button.
7. Press the “>”  or “<”  buttons button to review your test result history.
8. To view the sequence of test results in the memory, continue to press the “>”  or “<”  buttons.

NOTE:

- If you do not press the “M” button within 1 minute, the meter will turn off automatically.
- At any point in Memory mode if you want to shut the meter off, press the  button the meter will turn off and all settings will be automatically saved.
- Results from tests with control solution are not included in calculating the 7, 14, 21 or 28 day Averages.

Viewing Date, Time or Temperature

1. Press the “<” button
2. The date, time and clock symbol will be shown on the screen for 3 seconds and the meter will turn off automatically.



3. If the alarm has been set, the alarm symbol will be shown on the screen.



4. Press the “>” button and the temperature, and thermometer symbol will be shown on the screen for 3 seconds and the meter will turn off automatically.

NOTE:

To quickly adjust a certain number, keep pressing the “>”  or “<”  button until the one you want appears. At any steps if you want to shut the meter off, press the  button for about 3 seconds and all setting will be automatically saved.

Alarm Notes

1. The alarm duration is 30 seconds.
2. You can press any button and the alarm will stop.
3. Alarm will activate only in sleep mode. The alarm will not function while the meter is in use.

BLOOD SAMPLING AND TESTING

Fingertip Blood Sampling



1. Wash hands in warm, soapy water. Rinse well and dry thoroughly.
2. Press a single use lancet device firmly onto the chosen site and draw a sufficient blood sample.
3. Dispose of lancet device in a suitable sharps container.

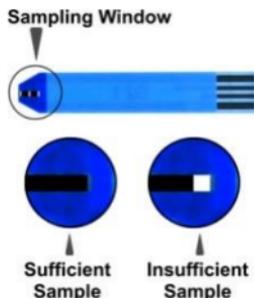
NOTES

- Only an auto-disabling, single use lancet device should be used.
- A new pair of clean gloves should be worn by the user before testing each patient.
- Please refer to the section of “How to Clean Your Device’ for more detailed information on Cleaning and Disinfection.
- You should wash hands thoroughly with soap and water after handling the meter, lancet device, or test strips.
- For more detailed information on cleaning and disinfection refer to “How to Clean and Disinfect Your Device.”

- *The blood-borne pathogen (e.g. HBV, HCV, or HIV) may be transmitted if there is shared using of a medical device.*
- *The lancet device is intended to be used by a single person and should not be shared.*
- *You should wash hands thoroughly with soap and water after handling the meter, lancet device, or test strips.*
- *Please refer to the section of “How to Clean and*
- *Disinfect Your Device” for more detailed information on Cleaning and Disinfection.*

Testing Your Blood Glucose

1. Take one **MediSure** test strip out of the test strip vial. Replace the vial cap immediately and close it tightly.
2. Insert this test strip with the black bars facing up into the test strip port of the meter. The meter turns on automatically.
3. You can also press the  button to turn on the meter, and a test strip symbol will instruct you to insert a test strip. Insert test strip within 1 minute.
4. You have 3 minutes to apply the blood sample. If you do not apply the sample within 3 minutes, the meter will turn off automatically.
5. Place the lancing device against the fingertip and press the trigger.
6. Pick up the meter and touch the blood drop to the edge of the application point of the test strip. The blood will be drawn into the test strip automatically. You will hear a beep letting you know the countdown has begun.
7. Look at the sampling window on the test strip. If you have enough blood on the strip, you will not see any white. The sampling window will be completely filled with blood. If it doesn't have enough blood,



- it will look like the illustration on the right above.
- When you hear a beep, the meter starts to count down from 6 seconds. After the countdown, the test result is displayed with date and time, and stored in the meter's memory.
 - If the test result is 13.3 mmol/L or higher, then an exclamation mark **!** will be displayed on the screen.
 - Record the result in your Log Book.
 - Remove the test strip from the meter. Discard the used test strip and lancet in a puncture-proof container.

CAUTION:

When a result either falls in a hypoglycemic range, <2.8 mmol/L, or in the hyperglycemic range >13.9 mmol/L follow the steps below.

If you get a high or low reading:

- Repeat the test.
- Test your meter using control solution.
- If you still get a high or low reading, contact your health care professional.

The meter should be wiped with suitable disinfectant by following the directions in the section *“How to Clean and Disinfect Your Device”*.

Testing Control Samples

Prepare the test strip and Glucose Control Solutions.



1. Press the  button. The meter will power on.
2. Insert **MediSure** strip into the strip port.
3. Press the  button to enter control mode. The button “L1” refers to Level 1. You can select L1, L2 or blood by pressing the  or  button.
4. When the control bottle symbol  flashes on the meter, it means that you can start a control test. You have 3 minutes to apply the control solution. If you do not apply the control solution within 3 minutes the meter will turn off automatically.
5. Use a clean, wet tissue to wipe the strip vial cap top. Dry thoroughly.
6. Roll Control Solution Bottle between hands to ensure proper distribution of solution and open cap.
7. Gently squeeze a drop onto the strip vial cap top.
8. Let the tip of the test strip touch the control solution drop.
9. Allow the solution to be automatically drawn into sampling window until it is completely filled.
10. After 6 seconds, the result will be shown on the screen.
11. Compare the control test result with the range printed on the label of the test strip vial.

Note

In the control mode (L1 or L2), the test result will not be stored in the meter's memory. For detailed information please refer to the Glucose Control Solution instructions.

When Control Solution Tests are Recommended

- A new Vial of test strips is opened.
- You receive a new lot of test strips.
- You suspect that the meter or test strips have issues.
- Results vary significantly, or are unexpected.

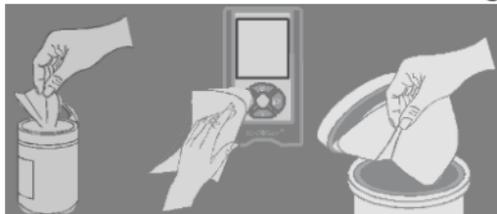
HOW TO CLEAN AND DISINFECT YOUR DEVICE

STEP 1: Clean Before Disinfecting



1. Dispense CaviWipes towelette.
2. Clean surface of your device with towelette to remove debris and bio burden.
3. Discard used towelette.

STEP 2: Disinfect After Cleaning



1. Dispense CaviWipes towelette.
2. Disinfect pre-cleaned surface with towelette for 2 minutes.
3. Discard used towelette.

Notes

1. Disinfect meter between each patient use.
2. After disinfection, user's gloves should be removed and hands washed before proceeding to the next patient.
3. The number of times the device can be cleaned and disinfected has been tested for up to 18,250 cycles. The recommended frequency to clean and disinfect in a multi patient setting is after each patient.
4. If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be disinfected prior to use by the second user.
5. Wash hands thoroughly with soap and water after handling the meter, or test strips.

Why is the disinfection of this device required?

Health Canada has issued new regulations regarding public health notifications highlighting the risk of transmission of disease from shared use of finger stick (lancing) devices, and point-of-care blood testing devices (blood glucose meters).

An **important** step in these regulations is to prevent a blood-borne pathogens being transmitted if there is shared use of a medical device. (e.g. Blood Glucose Meters and test strips).

The use of a 10% bleach solution is effective against viruses such as hepatitis B, but may lead to physical degradation of the meter. Following the disinfection protocol outlined below will prevent blood-borne pathogen transmission and ensure the device is not damaged.

For more information, please see

<http://hlicensed.medisure.ca>

Parts of the medical devices that require cleaning and disinfection



1. Whole Case
2. Display Cover
3. Buttons

**WE RECOMMEND THAT THE ENTIRE DEVICE BE
DISINFECTED**

Information of CaviWipe disinfectant

CaviWipes Disinfecting Towelettes are purchased from METREX RESEARCH CORP. The Health Canada DIN is 02246012 and the EPA Reg. is 46781-8. CaviWipes are non-woven disposable towelette pre-saturated with CaviCide, and are intended for use in health care settings such as hospital, dental offices, laboratories, clinics, ophthalmic offices, veterinary facilities and in kitchens and bathrooms. CaviWipes are effective against the Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV-1). The time to kill above viruses is 2 minutes.

Diisobutyl-phenoxy-enthoxyethyl dimethyl benzyl ammonium chloride is the active ingredient for using in CaviWipes Disinfecting Towelettes. It has been shown to be safe for the use the **MediSure** Blood Glucose Meter.

Manufacturer: METREX RESEARCH CORPORATION.

Address: 28210 Wick Road Romulus, MI 48174

Tel: 1-(800) 841-1428 Website: www.metrex.com

*You can call the service line or go to the website of METREX for purchase information. If you still have questions on the section “How to Clean and Disinfect Your Device”, please contact the **MediSure** Customer Assistance line 1-855-634-7873 for assistance.*

IMPORTANT NOTES

Caring For Your Meter

Taking care of your meter is important.

Please follow the guidelines shown below :

1. Do not disassemble your meter. If you have any questions, please contact MediSure.
2. Please use your meter carefully. Avoid throwing, shaking, or dropping it, which may cause damage.
3. Clean the meter's surface – refer to “How to Clean and Disinfect Your Device”
4. Do not wash or pour liquid on the meter.



Handling & Storage

1. Handle your meter with care and protect it from direct sunlight or extremely high or low temperature.
2. Do not expose your meter and test strips to an environment of high humidity, such as in bathrooms, kitchens, etc.
3. Keep your meter free of dust.
4. It is recommended that you use the carrying case that is designed to store and protect your **MediSure** Blood Glucose Monitoring System.
5. Put your system in an appropriate operating environment at least 30 minutes before testing.

Explanation of Displays

All-symbol Message:



When you press the  button or insert a test strip into the meter, all symbols will be displayed together for 2 seconds. Then the meter turns on automatically.

No Memory in the Meter Message:



If there is no memory in the meter, you press   button two times and the meter will show "0 Mem".

Sample Application Message:

This requires you to apply the blood sample or control solution to the test strip after inserting a test strip.



Apply Blood sample

Apply Control solution L1

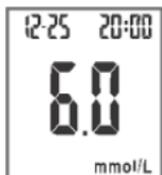
Apply Control solution L2



Test Result

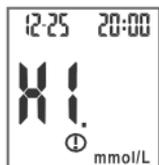


Message:



The meter shows results ranging from 1.1 to 41.7 mmol/L with respective dates and times.

HI Message:



If the test result is higher than 41.7 mmol /L the “HI” message is displayed.

Lo Message:



If the test result is lower than 1.1 mmol /L the “Lo” message is displayed.

ERROR MESSAGES AND TROUBLESHOOTING

When you operate the meter incorrectly, error messages are displayed. Each message is defined below.



Causes:

1. Test strip was removed during testing.
2. Damaged or used test strip was used.
3. The blood sample was applied before inserting the test strip.
4. The blood sample or control solution was applied without the blood drop or control bottle symbol flashed.

Action:

1. Do not remove the test strip before the result is displayed.
2. Repeat the test with a new test strip.
3. Insert the test strip into the meter first and then apply the blood sample.
4. Apply the blood sample or control solution after the blood drop or control bottle symbol flashes.



Cause:

The system is operating outside the appropriate temperature range 10°~40°C.

Action:

Move your meter and test strips to a place where the temperature is appropriate for running a test. Wait at least 30 minutes and test again.



Cause:

The battery is low.

Action:

Replace the battery soon.

For any of the Following Errors:



Action:

Contact: **MediSure** for any of these four errors.

EXPECTED VALUES¹

Expected blood glucose levels for people without diabetes:	
Time	Range (mmol/L)
Fasting	< 7.0
Two Hours After Meal	< 11.1

¹American Diabetes Association: Diabetes Care, Volume 35, Supplement 1, January 2012, S4

METER WARRANTY

Medi+Sure Canada Inc. warrants, to the original purchasers of the **MediSure** Blood Glucose Meter, that your meter shall be free of defects in materials and workmanships under a life time warranty from the date of purchase. If the **MediSure** meter does not work properly because of defects in materials or workmanships, Medi+Sure Canada Inc. will replace It with an equivalent product or repair it at no cost to the purchaser.

This warranty does not apply to the battery supplied with the meter or to a meter that has been modified, altered, abused, or misused in any way. Medi+Sure Canada Inc. shall not be responsible for any incidental or consequential damages.

NO OTHER WARRANTIES, EXPRESS, OR IMPLIED ARE MADE.

Please contact **MediSure** at 1-855-634-7873 for assistance if you have any questions about the warranty service.

NOTES:
