

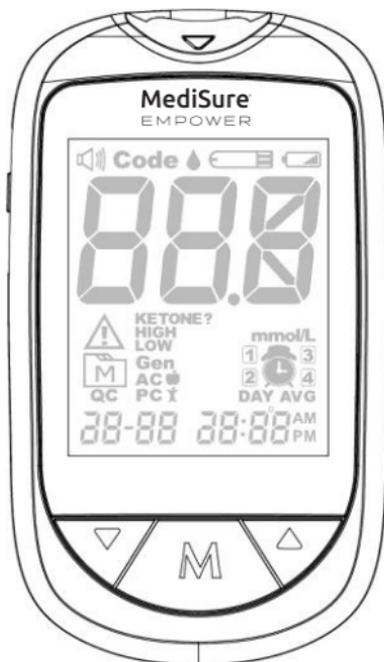
MediSure[®]

EMPOWER



Blood Glucose Monitoring System (DGEMP01M)

Owner's Manual



Dear MediSure Empower (DGEMP01M) System Owner:

Thank you for purchasing the **MediSure Empower Blood Glucose Monitoring System (DGEMP01M)**. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **MediSure Empower Blood Glucose Monitoring System (DGEMP01M)** to easily monitor your blood glucose levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Use

This MediSure Empower Blood Glucose Monitoring System (DGEMP01M) is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm and upper arm).

It should not be used for the diagnosis or screening of diabetes, or testing on the newborn.

This system is for single person use and should not be shared.

IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

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!

All parts of the kit are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

- “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)

<http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

- “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
5. The blood glucose test strip cannot be used for the testing of newborns.
6. Before using this device to test blood glucose, read all instructions thoroughly

and practice the test. Carry out all the quality control checks as directed.

7. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
8. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with accurate operation.
10. Proper maintenance and periodic control solution testing are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact the local customer service or place of purchase for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

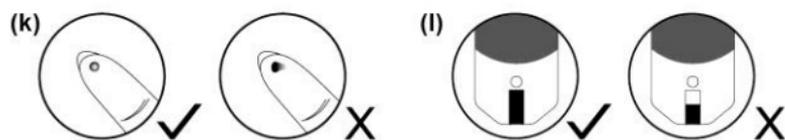
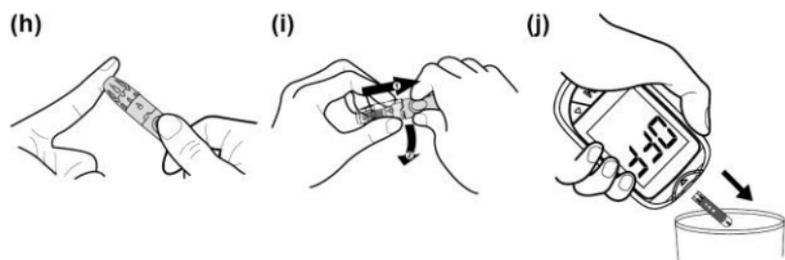
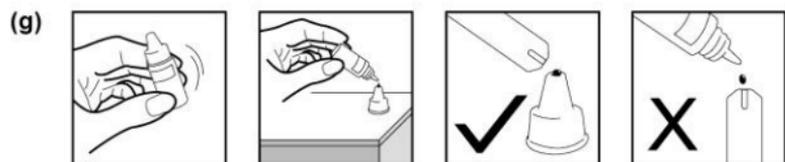
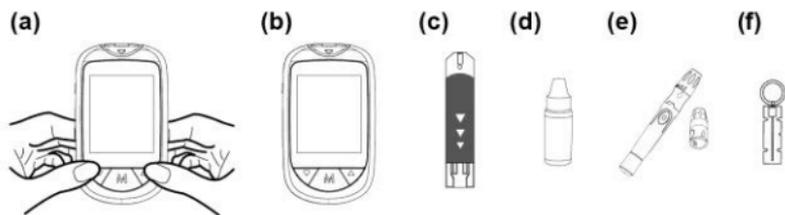


SCAN THIS QR CODE FOR ONLINE SUPPORT

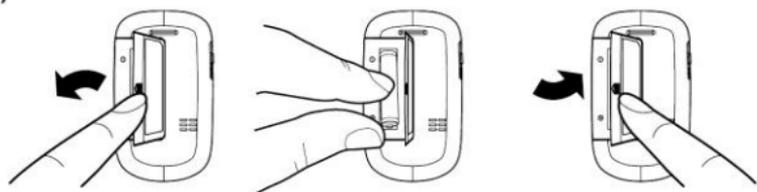
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BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose. Using other substances will lead to inaccurate results.
- If you are experiencing symptoms that are inconsistent you're your blood glucose test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- The device should not be used on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic- hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

● Limitation

The device should not be used on individuals in hyperglycemic-hyperosmolar state, with or without ketosis; not for neonatal use; not for use on critically ill patients.

Test Principle

Your system measures the amount of glucose in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Contents of System

Your new Blood Glucose Monitoring System kit includes the following:

1. MediSure Empower Blood Glucose Monitor (DGEMP01M) × 1
2. Owner's Manual × 1
3. Protective Wallet × 1
4. Lancing Device (DGEMP001L) × 1
5. Sterile Lancets (DGEMP030N) × 10
6. Log Book and Warranty Card x 1
7. Quick Start Guide × 1

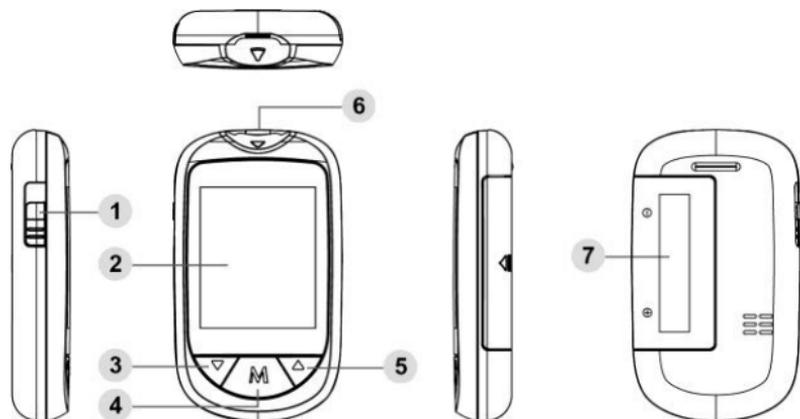
Glucose Control Solution (DGEMP01C Low W2 + High B3) × 1
MediSure Empower Blood Glucose Test Strips (c), glucose control solutions (d), lancing device (e), or sterile lancets (f) may not be included in the kit. They can be purchased separately. Please make sure you have those items needed for a test beforehand.

The strip port cable is not provided in the kit but an accessory for the data transmission feature connecting to your PC (see section "Downloading Results onto your Computer"). Please contact local customer services or the place of purchase for obtaining the cable.

NOTE:

If any items are missing from your kit or it was opened prior to use, please contact customer service at 1-855-634-7873 or customerservice@medisure.ca or contact your place of purchase for assistance.

Meter Overview



1. Test Strip Ejector

Eject the used strip by pushing up this button.

2. Display Screen

3. Down Button (▼)

4. M Button (M)

Enter the meter memory and silence a reminder alarm.

5. Up Button (▲)

6. Test Strip Slot / Strip Port Communication

Insert test strip here to turn the meter on for testing.

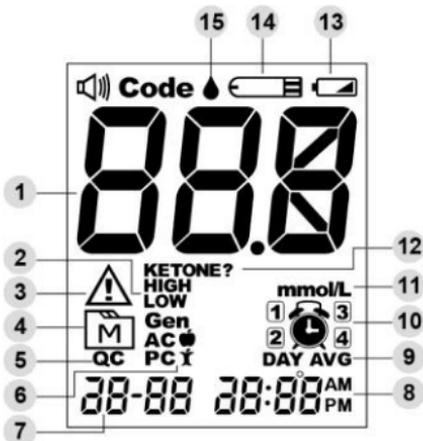
Connect strip port cable for data transmission.

7. Battery Compartment

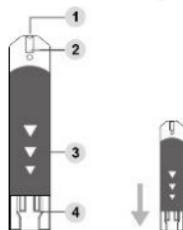
Display Screen

- 1 **Test Result**
- 2 **Low/High Symbol**
- 3 **Error Message**
- 4 **Memory Mode**
- 5 **QC Mode**
QC- control solution test
- 6 **Measuring Mode**
AC – before meal
PC – after meal
Gen – any time of day
- 7 **Date**
- 8 **Time**
- 9 **Day Average**
- 10 **Alarm Symbol**
- 11 **Measurement Unit**
- 12 **Ketone Warning**

- 13 **Low Battery Symbol**
- 14 **Test Strip Symbol**
- 15 **Blood Drop Symbol**



Test Strip



- 1 **Absorbent Hole**
- 2 **Confirmation Window**
- 3 **Test Strip Handle**
- 4 **Contact Bars**

ATTENTION:

The front side of test strip should face up when inserting test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

The **MediSure Empower Blood Glucose Monitoring System (DGEMP01M)** should only be used with **MediSure Empower Blood Glucose Test Strips (DGEMP01S or DGEMP01F)**. Using other test strips with this meter can produce inaccurate results.

SETTING THE METER

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

Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press and hold ▲ and ▼ at the same time.

1. Setting the date

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press ▲ or ▼ to select the correct number. Press **M**.

2. Setting the time format

Press ▲ or ▼ to select the desired time format (12h or 24h). Press **M**.

3. Setting the time

With the HOUR / MINUTE flashing in sequence, press ▲ or ▼ to select the correct number. Press **M**.

4. Setting the low and high target range for measuring mode

The sequence of the low and high target range setting is: Gen low → Gen high → AC low → AC high → PC low → PC high. With the settings mentioned above flashing in sequence, press ▲ or ▼ until the desired target appears. Press **M** to confirm.

5. Setting the beep sound On/Off

With the  flashing, press ▲ or ▼ to set the beep sound On or Off. Press **M** to confirm.

6. Deleting the memory

With “dEL” and “” on the display, press ▲ to select “no” to keep the results in memory, and then press **M**. To delete all the results, press ▲ to select “yes”, and then press **M** to delete all the memory records.

7. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display “On” or “OFF” and . If you don't want to set an alarm, press ▲ or ▼ to select “OFF”, and then press **M** to skip this step. Or select “On” and press **M** to proceed.

With the hour/minute flashing in sequence, press ▲ or ▼ to select the correct hour/minute. Press **M** and go to the next alarm setting.

NOTICE:

When the alarm beeps, press **M** to switch it off. Otherwise, it will beep for 2 minutes then switch off.

Congratulations! You have completed all settings!

NOTE:

- These parameters can ONLY be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE FOUR MEASURING MODES

The meter provides you with four modes for measuring, General, AC, PC and QC. You can switch between each mode by:

1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing “” and “Gen”.
2. Press **▲** to switch between General, AC and PC mode.
3. Press **M** to switch to QC mode.

CONTROL SOLUTION TESTING

Do a control solution test when:

- You first receive the meter
- At least once a week to routinely check the meter and test strips
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process, or
- You have dropped or think you may have damaged the meter.

Performing a Control Solution Test

To perform a control solution test, you will need: **(b)**, **(c)** and **(d)**.

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display the “” and “”.

2. **Press M to mark this test as a control solution test**

With “**QC**” displayed, the meter will store your test result in memory under “**QC**”. If you press **M** again, the “**QC**” will disappear and this test is no longer a control solution test.

Warning:

When doing the control solution test, you have to mark it so that the test results will **NOT** mix with the blood glucose **TEST RESULTS** stored in the memory. Failure to do so will mix up the blood glucose test results with the control solution test results in memory.

3. **Apply control solution (g)**

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

NOTE:

To avoid contaminating the control solution, do not directly apply control solution onto a strip.

4. **Read and compare the result**

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Go to www.medisure.ca/support or call customer service at 1-855-MDI-SURE for help.

NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the **MAINTENANCE** section for important information about your control solutions.

TESTING WITH BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the “**Cleaning and Disinfection**” section.

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Lancing device must not be used for more than one person.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction significantly reduces variations between measurements.

Please follow the suggestions below before obtaining a drop of blood:

● **Wash and dry your hands before starting.**

● Select the puncture site either at fingertips or another body parts (please see section “Alternative Site Testing” (AST) on how to select the appropriate sites).

● Rub the puncture site for about 20 seconds before penetration.

● Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.

● Use a clear cap (included in the kit) while setting up the lancing device.

● **Fingertip testing (h)**

Press the lancing device’s tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.

● **Blood from sites other than the fingertip (i)**

Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, or hand, avoid lancing the areas with obvious veins because of excessive bleeding.

NOTE:

● Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

● Please consult your health care professional before you begin AST.

● It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a Blood Glucose Test

To perform a blood glucose test, you will need: **(b)**, **(c)**, **(e)** and **(f)**.

1. Insert the test strip to turn on the meter

Wait for the meter to display the “” and “”.

2. Select the appropriate measuring mode by pressing M.

3. Obtaining a blood sample (k)

Use the pre-set lancing device to puncture the desired site. Wipe off the first appeared drop of blood with a clean cotton swab.

The size of the drop should be at least as big as • (actual size), which is 0.5 microliter (μL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

4. Apply the sample (l)

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

5. **Read Your Result**

The result of your blood glucose test will appear after the meter counts down to 0. The blood glucose result will be stored in the memory automatically.

6. **Eject the used test strip (j)**

Eject the test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING:

- The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination. For more information, please refer to the “Cleaning and Disinfection” section.

Alternative Site Testing

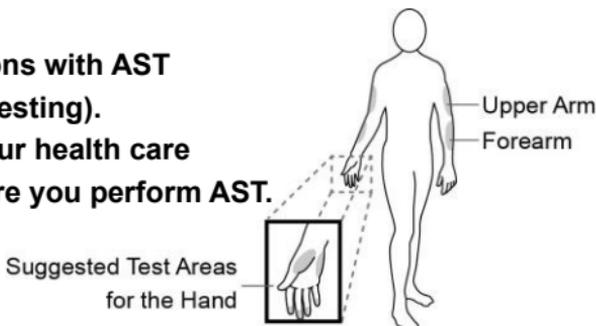
You can test on a variety of locations on your body.

Important:

There are limitations with AST

(Alternative Site Testing).

Please consult your health care professional before you perform AST.



When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing blood glucose during or immediately after a meal, physical exercise, or any other event, **take a blood sample from your finger only.**

We strongly recommend that you perform AST **ONLY** at the following times:

- 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.

Do NOT use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia
- You are testing for hyperglycemia
- Your AST results do not match the way you feel.
- Your routine glucose results often fluctuate.

METER MEMORY

The meter stores the 1000 most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off**.

Reviewing Test Results

1. **Press and release M or ▲.**

“**M**” will appear on the display and the first reading you see is the last blood glucose result along with date, time and the measuring mode.

2. **Press ▲ or ▼** to recall the test results stored in the meter each time you press. Press and hold **M** to switch off the meter.

Reviewing Blood Glucose Day Average Results

1. **Press and release ▼** to enter memory mode for average results with “**M**” and “**DAY AVG**” displayed on the screen. Release **M** and then your 7-day average result measured in general mode will appear on the display.

2. **Press ▲ to review** 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, then PC.

3. **Exit the meter memory.**

Keep pressing the **M** and the meter will turn off after displaying the last test result.

NOTE:

- Any time you wish to exit the memory, keep pressing **M** for 3 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

DOWNLOADING RESULTS ONTO A COMPUTER, TABLET OR SMART PHONE

Data Transmission via Cable or Bluetooth Dongle

You can use the meter with a strip port cable (optional) and the Health Care Software System to view test results on your personal computer, tablet or smart phone. To learn more about the Health Care Software System or to obtain a strip port cable separately, please contact Customer Service at 1-855-634-7873 or customerservice@medisure.ca or your place of purchase for assistance.

1. Obtaining the required cable or Bluetooth Dongle and installing the software

To download the Health Care Software System, please visit the MediSure website: www.medisure.ca/support

2. Connecting to a personal computer

(a) For Computer, connect the strip port cable to a cable port on your computer. With the meter switched off, insert the other end of the strip port cable to the meter data port. "PC" will appear on the meter display, indicating that the meter is in communication mode.

(b) For Bluetooth, instructions will come with the Bluetooth Dongle and should be followed separately.

3. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with date and time. Remove the cable and the meter will automatically switch off.

WARNING:

While the meter is connecting to the PC, it will be unable to perform a blood glucose test.

MAINTENANCE

Battery

Your meter comes with one 1.5V AAA size alkaline battery.

Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

1. The “” **symbol appears** along with display messages: The meter is functional and the result remains accurate, but it is time to change the battery.
2. The “” **symbol appears with E-b, Error and low:** The power is not enough to do a test. Please change the battery immediately.

Replacing the Battery

To replace the battery (m), make sure the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old battery and replace with one 1.5V AAA size alkaline battery.
3. Close the battery cover. If the battery is inserted correctly, you will hear a “beep” afterwards.

NOTE:

- Replacing the battery does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Battery might leak chemicals if unused for a long time. Remove the battery if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the battery according to your local environmental regulations.

Cleaning and Disinfection

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

Why the cleaning and disinfection should be performed

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

When to clean and disinfect the meter

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

How to clean and disinfect the meter

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt, blood, or any other body fluid with the wipe. Use a second wipe to disinfect the meter by following the disinfecting procedure below. Do NOT use organic solvents to clean the meter.

We recommend for meter cleaning and disinfection you should use the disinfecting wipe from below, which the active ingredients have been tested to be effective against Hepatitis B Virus (HBV) for the meter. The wipe has been shown to be safe for use with the meter.

✓ [Clorox Healthcare™ Bleach Germicidal Wipes \(DIN 02465671\)](#)

Disinfecting Procedures

For the meter:

1. Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
2. Wipe all meter's exterior surface display and buttons. Hold the meter with the test strip slot pointing down and wipe the area around the test slot, but be careful not to allow excess liquid to get inside. **Keep meter moist with disinfection solution for a minimum of 1 minute for the wipes.** Follow the instructions on the package label of disinfecting wipe. Use two or more wipes if necessary. (n)
3. Allow the meter surface to dry completely.
4. Discard the used wipes and never reuse them.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact the MediSure Customer Care at 1-855-MDI-SURE for assistance.

Stop using the meter if you see any signs of deterioration. For example:

- meter cannot be turned on
- LCD display cracks or becomes cloudy
- buttons no longer function
- meter outer casing cracks
- color or paint/printing on housing is abnormal
- scratches or abrasions on meter are higher than acceptable

Please call the MediSure Customer Care at 1-855-634-7873 for a replacement meter if any of the signs of deterioration are noticed.

NOTE:

- Do **NOT** clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do **NOT** allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it.
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

For the lancing device:

1. Take out one disinfecting wipe from the container.
2. Clean exposed surfaces of the lancing device thoroughly and remove any visible dirt, blood, or any other body fluid with the wipe.
3. Take out second disinfecting wipe from the container. Keep the surface of lancing device wet with disinfection solution for a minimum of 1 minute.
4. Allow the surface to dry completely.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact customer service or place of purchase for assistance.

This device has been validated to withstand 260 cycles (10,950 cleans), of cleaning and disinfection, using the recommended disinfecting wipe, to simulate one cleaning and disinfection cycle per week over 5 years of use.

The lancing device has been validated to withstand 110 cycles of cleaning and disinfection, using the recommended disinfecting wipe, to simulate one cleaning and disinfection cycle per week over 2 years of use.

The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first. Stop using the meter if you see any signs of deterioration. For example:

- meter cannot be turned on
- LCD display cracks or becomes cloudy
- buttons no longer function

- meter outer casing cracks
- color or paint/printing on housing is abnormal
- scratches or abrasions on meter are higher than acceptable

Please contact the Customer Service for a replacement meter if any of the signs of deterioration are noticed.

Meter Storage

1. Storage conditions: -20°C to 60 °C (-4°F to 140°F); below 93% relative humidity.
2. Always store or transport the meter in its original storage case.
3. Avoid dropping and heavy impact.
4. Avoid direct sunlight and high humidity.

Caring for Your Test Strips

- Storage conditions: 2°C to 30°C (35.6°F to 86.0°F); 10% to 85% relative humidity. Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date. This may cause inaccurate results.
- 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 may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only our control solutions with your meter.
- Do not use the control solution beyond the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do **NOT** freeze.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

Result Readings

MESSAGE	WHAT IT MEANS		
Lo	< 1.1 mmol/L		
LOW	1.1 to 3.8 mmol/L		
5.5 mmol/L	AC	PC	Gen
	3.8 - 7.1 mmol/L	3.8 - 9.9 mmol/L	3.8 - 6.6 mmol/L
HIGH	AC	PC	Gen
	7.2 - 13.2 mmol/L	10 - 13.2 mmol/L	6.6 - 13.2 mmol/L
KETONE?	≥ 13.3 mmol/L "KETONE?" is shown when your blood glucose result is equal to or higher than 13.3 mmol/L.		
	What to Do: Check blood ketone if checking ketones is part of your diabetes management program.		
Hi	> 36.1 mmol/L		

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the battery is too low.	Replace the battery immediately.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 8°C to 45°C (46.4°F to 113°F). Repeat the test after the meter and test strip are in the above temperature range.
E-0 E-A E-E	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-F	Appears when test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing "💧" appears on the display.
Defective meter.	Please contact customer services.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 20°C to 25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test strip.	Please contact customer services.

DETAILED INFORMATION

The Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without diabetes (mmol/L)
Fasting and before meal	< 5.6 mmol/L
2 hours after meals	< 7.8 mmol/L

Source: American Diabetes Association. Standards of medical care in diabetes- 2016; 39 (supp.1 Diabetes Care): S16.

Please consult your health care provider to determine a target range that works best for you.

Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before going to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

While staying at the lab:

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray-top test tube.
- Use fresh capillary or venous blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress^{*2}. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 3.9 mmol/L higher than blood drawn from a vein (venous sample) used for a lab test^{*3}. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

*2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

*3: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
	In vitro diagnostic medical device		Batch code
	Consult instructions for use		Manufacturer
	Temperature limitation		Serial number
	Use by		Humidity Limitations
	Do not reuse		Caution, consult accompanying documents

SPECIFICATIONS

Model No.: DGEMP01M

Dimension & Weight: 90.3 (L) x 52.3 (W) x 18 (H) mm, 46.8 g
(without batteries)

Power Source: One 1.5V AAA alkaline battery

Display: LCD

Memory: 1000 measurement results with respective date and time

External Output: strip port cable communication

Auto sample loading detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature Warning

Operating Condition: 10°C to 40°C (50°F to 104°F), 10% to 85% R.H. (non-condensing)

Meter Storage/Transportation Conditions: -20°C to 60°C (-4°F to 140°F), below 93% R.H.

Test Strip Storage/Transportation Conditions: 2°C to 30°C (35.6°F to 86°F), 10% to 85% R.H.

Measurement Units: Fixed mmol/L

Measurement Range: 1.1 to 36.1 mmol/L

Expected Service Life: 5 years

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6.



SCAN THIS QR CODE FOR ONLINE SUPPORT

 **MediSure Canada Inc.**

785 Westney Rd. S Unit 23,
Ajax, ON L1S 7G1 CANADA

www.medisure.ca

Toll Free : 1-855-634-7873

(8:30 am-5:00 pm EST, Monday-Friday)

For assistance outside of these hours, please contact your healthcare professional.

(8:30 am-5:00 pm EST, lundi - vendredi)

Pour obtenir de l'aide en dehors de ces heures, contactez votre professionnel de la santé.

For self-testing.
Pour l'auto-test.

IVD

