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IMPORTANT INFORMATION: READ THIS FIRST!

To receive safe and optimum system benefits, please read the entire manual contents before using the system. Please note the following instructions:

Intended use:

Bravo[™] Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management of individual user effectively.

Bravo[™] Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). **Bravo[™]** Blood Glucose Monitoring System should not be used for the diagnosis of diabetes or for testing newborns. Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.

The following chart explains the symbols you'll find in the *Bravo*[™] User Manual, product packaging, and product inserts.

IVD For in vitro diagnostic use

Ŕ

CC⁰¹²³ This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices.

Cautions for safety and optimum product use

Do not discard this product with other household-type waste.

Consult instruction for u	ise Manufacturer
EC REP Authorized representat	ive 😟 Do not reuse.
LOT Batch code	SN Serial number
Use by	I Temperature limitations

IMPORTANT INFORMATION

- The *Bravo*[™] Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use).
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The *Bravo*[™] Meter detects this electrical current and measures the amount of glucose in the blood sample.
- The *Bravo*[™] Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The *Bravo*[™] Blood Glucose Meter should be used only with the *Bravo*[™] Test Strip.
- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
- If your test result is below 3.3 mmol/L or above 13.3 mmol/L, consult a healthcare professional immediately.
- The *Bravo*[™] Meter and lancing device are for single patient use. Do not share them with anyone including other family members.
- Inaccurate results may occur in severely hypotensive (having low blood pressure) individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic (high blood sugar) or hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

If you need assistance, please contact your authorized *Endomedical*[™] sales representative or visit **www. endomedical.ca** for more information.

SPECIFICATIONS

Product specifications		
Measurement range	1.1 ~ 33.3 mmol/L	
Sample size	Minimum 0.5 <i>µL</i>	
Test time	5 seconds	
Sample type	Fresh capillary whole blood	
Calibration	Plasma-equivalent	
Assay method	Electrochemical	
Battery life	1,000 tests	
Power	Two 3.0 V lithium batteries (disposable, type CR2032)	
Memory	250 test results	
Size	93 X 45 X 15 (mm)	
Weight	54 g (with batteries)	
Operating ranges		

Temperature	10 ~ 40°C (50 ~ 104°F)
Relative humidity	10 ~ 90%
Hematocrit	20 ~ 60%

BRAVO™ BLOOD GLUCOSE MONITORING SYSTEM



Components

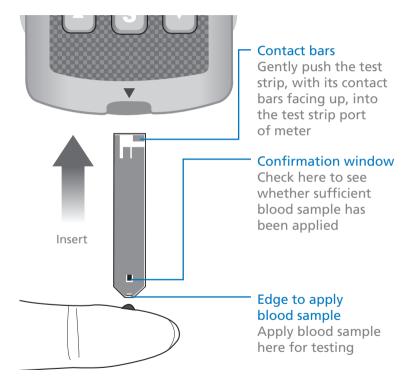
1 Bravo™ Blood Gluo	cose Meter 7 Le	ogbook
2 Lancing Device	8 C	arrying Case
3 Lancets (10)	9 B	<i>ravo</i> ™ Blood Glucose
4 Owner's Booklet	Те	est Strips (10)
5 Quick Reference G	uide 🚺 B	atteries (2)
6 Warranty Card		

The components of the product are identical to what's listed in the meter manual, however you need to check the meter box for the quantity of strips.

- Please contact your authorized *Endomedical*[™] sales representative if any component is missing or damaged.
- The cable for data transmission can be ordered separately. Please contact your authorized *Endomedical*[™] sales representative or visit **www.endomedical.ca**.

BRAVO™ BLOOD GLUCOSE TEST STRIP

The **Bravo**[™] blood glucose monitoring system measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the strip.



WARNING!

- The *Bravo*[™] test strip should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration or discard date.
- Check the expiration date printed on the vial. When you first open a test strip vial, you must record the discard date (date opened plus six months) in the space provided on the label.
- Store test strips in a cool and dry place at a temperature of 1 \sim 30°C (34 \sim 86°F).
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip for testing and use the strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the *Bravo*[™] test strip package insert.

IMPORTANT NOTE:

Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). In some countries, the meters are preset to display unit in mg/dL (milligrams of glucose per deciliter).

Check your display to ensure that results are being displayed in mmol/L. If they are not, contact *Endomedica*/™ at 1-800-282-6542.



Keep the meter and testing supplies away from young children.

BRAVO™ GLUCOSE METER

BRAVO™ BLOOD GLUCOSE METER DISPLAY

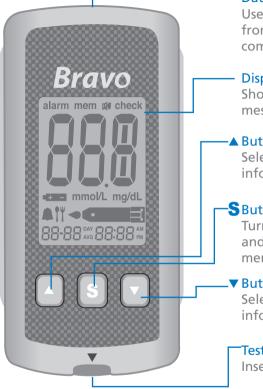
alarm mem 🕫 check

+ – mmol/L mg/dL

88-88 PAY 88-88 PM

Hour Minute

Month Dav



Data Port

Used to transfer data from the meter to a computer with a cable

Display Shows results.

messages

▲ Button

Selects or changes information

SButton

Turns the meter on/off and confirms menu selections

▼ Button

Selects or changes information

Test Strip Port

Insert test strip here



The cable for data transmission to PC can be ordered separately. Please contact your authorized Endomedical[™] sales representative or visit www. endomedical.ca.

mem -

appears when test results stored in the memory are displayed

alarm -

appears when the time alarm has been set

Battery icon indicates meter battery is running low and needs to be replaced

Post-meal test flag appears during post-meal testing and when postmeal test results are displayed Alarm icon -

appears when the post-meal alarm has been set

Sound icon

appears only when the sound is set to OFF

check

appears when test results have not been saved

Test results test results displaying panel

Decimal point

appears when the blood glucose measuring unit is set to mmol/L

– mmol/L, mg/dL unit for measuring blood glucose

Blood insertion icon

indicates meter is ready for the application of a drop of blood or control solution



Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). In some countries, the meters are preset to display unit in mg/dL (milligrams of glucose per deciliter). Check your display to ensure that results are being displayed in mmol/L. If they are not, contact Endomedical at 1-800-282-6542.

SETTING UP YOUR SYSTEM

Press and hold the **S** button for 3 seconds to enter the SET mode. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter.

Press \blacktriangle or \blacktriangledown to reach the accurate value. Press and hold \blacktriangledown to scroll faster.

ADJUSTING THE DATE AND TIME

Entering the SET Mode

Press and hold the **S** button for 3 seconds to enter the SET mode. After all the segments flash across the screen, the 'SET' character will be displayed on the screen.



Press the **S** button again to enter the year setting mode.

Setting the Year

Press and release ▲ or ▼ to adjust until the correct year appears. Press and hold ▼ button to scroll through the numbers quickly.

After setting the year, press the **S** button to confirm your selection and enter the month setting mode.



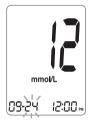
Setting the Month

A number indicating the month will be blinking on the left corner of the screen. Press ▲ or ▼ until the correct month appears. Press the **S** button to confirm your selection and enter the date setting mode.



Setting the Date

Press \blacktriangle or \checkmark until the screen displays the correct date. Press the **S** button to confirm the date and enter the time setting mode.



Setting the Time

The meter can be set in the AM/PM 12hour or the 24-hour clock format. Press ▲ or ▼ to select a format. The AM/PM icon is not displayed in the 24-hour format. After selecting the format, press the **S** button to enter the hour setting mode.



6 Setting the Hour

Press \blacktriangle or \checkmark until the correct hour appears. After the hour is set, press the **S** button to enter the minute setting mode.



Setting the Minute

Press \blacktriangle or \checkmark until the correct minute appears. After setting the minute, press the **S** button to enter the sound setting mode.



Setting the Sound On/OFF

On pressing \blacktriangle or \bigtriangledown , the screen will display On or OFF. Press the **S** button to confirm the selection.

The meter will beep in the following instances if set to On.

- When the test strip is inserted in the meter
- When the blood sample is absorbed into the test strip and the test starts
- When the test result is displayed
- When you push the **S** button or ▲ button to turn on the meter
- 68 EP
- When you push the **A** button to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test

If the sound is set to OFF, none of the sound functions will work.



58 E P





Only when the sound is set to OFF, 🖤 icon appears on the display.

CHECKING THE SYSTEM

9 Setting the 'Test Result Reset' (Deleting all the saved test results)

In this mode all the test results stored in the meter can be deleted. Please note that if you select YES, all the stored test results will be deleted and cannot be restored.

After the beeper mode is set, press the **S** button to enter the 'Test Result Reset' mode. The 'dEL' character will blink on the screen.

Press \blacktriangle or \triangledown to alternate between 'YES' or 'no'.

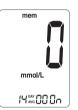
To delete all the stored test results, press the **S** button while the screen displays 'YES'. Then, all the test results stored in the meter will be deleted and the screen will be similar to the picture on the right.

If you do not want to delete the results, press the **S** button while the screen displays 'no'. Then, the screen will return to step 2. See page 12.

Note

At any stage, if the **S** button is pressed for 3 seconds, setting mode will finish and the meter will be turned off. Press and hold ▼ to scroll through numbers quickly.







You may check your meter and test strips using the **Bravo™** Control Solution (control A and/ or B). The **Bravo™** Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.

The test strip vials have **Bravo**[™] Control Solution ranges printed on their labels. Compare the result displayed on the meter to the **Bravo**[™] Control Solution range printed on the test strip vial. Before using a new meter or a new vial of test strips, you may conduct a control solution test following the procedure on pages 18 ~ 19.

Notes:

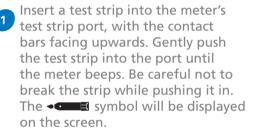
- Use only the *Bravo*[™] Control Solution.
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus 3 months) in the space provided on the label.
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20 ~ 25°C, 68 ~ 77°F).
- Before using the control solution, shake the bottle, discard the first few drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature of 8 ~ 30°C (46 ~ 86°F).

You may do a control solution test:

- When you want to practice the test procedure using the control solution instead of blood,
- When using the meter for the first time,
- Whenever you open a new vial of test strips,

- If the meter or test strips do not function properly,
- If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly,
- If you drop or damage the meter.

CONTROL SOLUTION TESTING





Shake the *Bravo*[™] Control Solution bottle before each test. Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth. After the →

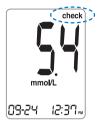
symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.

Note



A test result will appear after the meter counts down from 5 to 1.

After your control solution result appears on the display, press \triangledown for 3 seconds till the 'check' appears on the display. When the 'check' is displayed, the result is not stored in the meter's memory and is not included in the 14day averages.



Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within that range.

Used strips should be discarded safely in disposable containers.

CONTROL SOLUTION RANGE / SOLUTIONS DE CONTRÔLE Control A / Contrôle A : 5.8-8.4 mmol/L Control B / Contrôle B : 10.2-15.3 mmol/L





The range printed on the test strip vial is for the **Bravo**[™] Control Solution only. It does not have any connection to your blood glucose level.



The **Bravo™** Control Solution can be purchased separately. Please contact your authorized *Endomedical*™ sales representative.

Comparing the Control Solution Test Results

The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

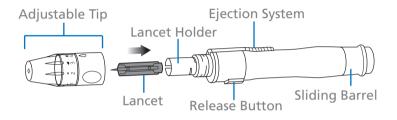
Situations	Actions
 When the control solution bottle was not shaken well, When the meter, test strip, or the control solution were exposed to high or low temperatures, When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean, When the meter is not functioning properly. 	Repeat the control solution test by referring to the "Notes" on page 17.
 When the control solution is past the expiration date printed on the bottle, When the control solution is past its discard date (the date the bottle was opened plus three (3) months), When the control solution is contaminated. 	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range printed on the test strip vial, the **Bravo**[™] Test Strip and Meter may not be working properly. Do not use your system and contact *Endomedical*[™] sales representative.

USING THE LANCING DEVICE

You will need a lancing device in order to collect a blood sample.

You may use the lancing device contained in the **Bravo**[™] Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device is intended for self testing by a single patient. It must not be used on more than one person due to risk of infection.
 - Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.



To avoid infection when drawing a sample, use a lancet only one time, and:

- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

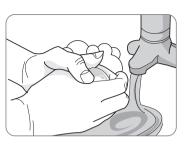


Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.

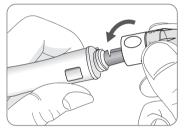
PREPARING THE LANCING DEVICE

1

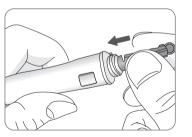
Wash hands and fingertip sample site with soap and warm water. Rinse and dry thoroughly.



2 Unscrew and remove the lancing device tip.



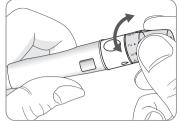
Firmly insert a new lancet into the lancet holder. Hold the lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.

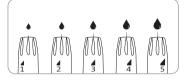


Select a desired depth of one-to-five (1-5) on lancing device's adjustable tip. Rotate ring to align desired number with arrow. A beginning setting of three (3) is recommended.

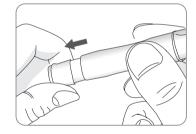
lancing device is cocked

when you feel a click.





5 To cock the lancing device, hold the body in one hand. Pull the sliding barrel on with the other hand. The



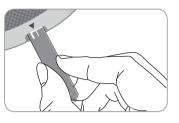
Note

The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration for an adequate sample size. A beginning setting of three (3) is recommended.

22 Bravo Blood Glucose Monitoring Sys

PREPARING THE METER AND TEST STRIP

APPLYING BLOOD SAMPLE



Flagging Post-meal Test Results

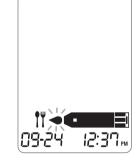
The meter allows you to flag a result of a post-meal test with $\uparrow \uparrow \uparrow$ icon. The post-meal test flag ($\uparrow \uparrow \uparrow \uparrow$) can be attached just before applying the blood sample. Once you attach the post-meal flag ($\uparrow \uparrow \uparrow \uparrow$) to the test results, it cannot be deleted.

If you want to attach a post-meal flag (**1**) to a test result, press and hold ▼ for 3 seconds after inserting the test strip.

The post-meal flag (1) and the

Symbol will appear on the screen. The test result will also be displayed with the post-meal flag (ĨĨ).

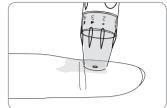
If you do not want to save the result as a post-meal test, move on to the step 8 after the step 6.

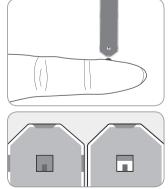


Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (Actual size of 0.5 μ L: •)

After the **•** symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window is not filled before the meter finishes counting down then discard the test strip and insert a new one.

If confirmation window is not filled in time because of abnormal viscosity or insufficient volume, Er4 message will appear.





Good Sample Insufficient Sample

DISCARDING USED LANCETS

Note

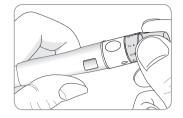
The meter may switch off if the blood sample is not applied within 2 minutes of the **and a** symbol appearing on the screen. If the meter turns off, remove the strip, reinsert it and start from step 6.

10 The test result will appear after the meter counts down from 5 to 1.

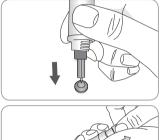
The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in disposable containers.



Unscrew lancing device tip.



Place protective cover on lancet. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.







The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

ALTERNATIVE SITE TESTING

What is Alternative Site Testing(AST)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it can be quite painful. When doing a glucose test, using different parts of the body such as the arms, palms, thighs, and calves can reduce the pain during testing. This method of testing with different parts of the body other than the fingertips is called Alternative Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternative Site for Testing



Alternative Site Blood Sampling (forearm, palm, thigh, calf)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternative site sampling. Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes color. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5 μ L, actual size: •) blood is drawn. Carefully lift the lancing device away from your skin.

THINGS TO KNOW WHEN USING AST

Please understand the following things before testing outside of the fingertip (arms, palm, thighs, calves). The capillary blood of the fingertip shows the change in glucose more rapidly than AST. Therefore, the test results from the fingertip test and AST may differ. This is because things such as lifestyle and ingested food have an effect on glucose levels. Vacuum-assisted lancing devices are useful in collecting blood from alternative sites. It is possible to use regular lancing devices for alternative sites by piercing deeper than when sampling from fingertips and pressing slightly against the skin.

ACCEPTABLE SITUATIONS FOR AST

- Fasting period
- Before a meal

SITUATIONS REQUIRING FINGERTIP TEST

- When the glucose levels are rapidly changing (during the two hours after a meal, insulin dose or exercise)
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognized (hypoglycemic unawareness)
- When insulin has the biggest effect
- 2 hours after an insulin injection
- If you think your blood glucose is low
- If you think you will be driving a car or operating machinery

AST PRECAUTIONS

HI AND LO MESSAGES

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect your opinion, retest using the fingertip test. If the test results do not reflect your opinion, please consult your healthcare professional.
- Do not rely on the AST results for changing your treatment method.
- The amount of glucose in alternative sites differs from person to person.
- Before using AST, please consult your healthcare professional.

Note

Results from alternative site and fingertip samples may differ from each other as there is a time lag for the glucose levels to reach the same value. Use a fingertip for drawing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.

Note

If the sample drop of blood runs or spreads due to contact with hair or with a line in you palm, do not use that sample. Try puncturing again in a smoother area.

HI Message

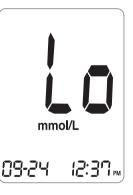
The meter displays results between 1.1 ~ 33.3 mmol/L. HI appears when the blood glucose level is more than 33.3 mmol/L and indicates hyperglycemia.

If the HI is displayed again on retesting, please contact your healthcare professional immediately.

Lo Message

Lo appears when the result is less than 1.1 mmol/L and indicates hypoglycemia.

If the Lo is displayed again on retesting, please contact your healthcare professional immediately. mmol/L 09-24 (2:37∞





Please contact your authorized *Endomedical*[™] sales representative if such messages are displayed even if you do not have hyperglycemia or hypoglycemia.

TARGET BLOOD GLUCOSE RANGES

Reminders	Vour torrot room from
Time of day	Your target ranges from your healthcare professional
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hours after meals	
Between 2 a.m. and 4 a.m.	

Blood Glucose Targets for Most People with Diabetes

A recommended target for fasting blood glucose or glucose before meals is 4.0 - 7.0 mmol/L. A recommended target for blood glucose 2 hours after eating is 5.0 to 10.0 mmol/L.

Reference

Canadian Diabetes Association, 2008. *Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada.*

These targets are intended to be a guide. Please discuss your blood glucose targets with your healthcare professional.

METER MEMORY

The meter can save up to 250 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

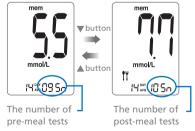
The meter calculates and displays the averages of total test results, pre-meal test results, and post-meal ($\uparrow\uparrow$) test results from the last 14 days.

VIEWING TEST RESULTS STORED IN THE METER'S MEMORY

Press the ▲ or **S** button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, followed by the average value and the number of the test results saved within the last 14 days.



Press ▼ to view the average value and the number of tests performed before eating a meal for the last 14 days. On pressing ▼ again, the average value and the number of tests performed post-meals for the same period will appear on the screen.



SETTING THE ALARM FUNCTION

3

Use the \checkmark button to scroll through the test results, starting from the most recent and ending with the oldest. Press \blacktriangle to return to the result seen previously.

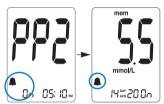
After checking the stored test result, press the **S** button to turn off the meter.

Four types of alarms can be set in the meter: one post-meal alarm (PP2 alarm) and three time-set alarms (alarm1 ~ 3). The PP2 alarm goes off 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing ∇ , \blacktriangle or the **S** button or by inserting a test strip.

SETTING THE POST-MEAL ALARM (PP2 ALARM)

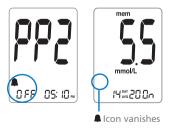
Setting the PP2 alarm On

Without inserting a test strip, press and hold \blacktriangle for 3 seconds to set the post-meal alarm. The 'PP2' character, the bell (\blacklozenge) icon and then the 'On' character will be displayed. The screen will then automatically change to the memory check mode. At this time, the bell (\blacklozenge) icon, indicating that the PP2 alarm has been set, will be displayed on the screen.



Setting the PP2 alarm OFF

To turn off the PP2 alarm, press and hold \blacktriangle for 3 seconds. The 'PP2'character, the bell (\blacksquare) icon and then the 'OFF' character will appear on the screen. Then the screen will change automatically to the memory check mode without the bell (\blacksquare) icon being displayed.





On pressing $\mathbf{\nabla}$, the latest test result saved in the meter's memory will be displayed on the screen along with the date and time. Press and hold $\mathbf{\nabla}$ to scroll through the test results.

SETTING THE TIME ALARMS (ALARM 1 ~ 3)

- Without inserting a test strip, press ▲ and the S button simultaneously for 3 seconds to enter the time alarm mode. The 'alarm1' will be displayed while the 'OFF' blinks on the screen.
- 2 On pressing ▼, the 'alarm1' is set and the 'On' is displayed on the screen. Press ▼ again to cancel the 'alarm1'. The 'OFF' will blink on the screen.

Press ▲ to adjust the time of the 'alarm1'. A number representing the time will blink on the screen. Press ▼ to set the time. Press ▲ to end.





0~ 02:00

alarm

On pressing ▲, the number indicating the minute will start blinking. Press ▼ to set the accurate minute



Press the **S** button to finish and to enter the 'alarm 2' mode. Repeat steps 2 to 5 to set the remaining time alarms (alarm 2 ~ 3).

alarm

flo.

Press the **S** button for 3 seconds to finish and turn the meter off.

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PUTTING IN OR REPLACING THE BATTERIES

The **Bravo**[™] Meter comes with two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty.

When the **H** icon appears on the display for the first time, the battery should be replaced as soon as possible.

The test results might not be saved if the battery runs out.

1 Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



2 Remove the old batteries one by one by lifting with the index finger and pulling with your thumb and index fingers as shown in the figure on the right. Insert two new batteries with the + side facing up and make sure the batteries are inserted firmly.

Place the cover on the battery compartment. Push down until you hear the tab click into place.







CARING FOR YOUR SYSTEM

Use a soft cloth or tissue to wipe the meter exterior. If necessary, the soft cloth or tissue might be dipped in a small amount of alcohol.

Do not use organic solvents such as benzene, or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.

Store all the meter components in the portable case to prevent loss.

Caution:

- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter in a cool and well ventilated place.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- **Bravo[™]** Meter should be used only with **Bravo[™]** strips.
- Store all the meter components in the portable case to prevent loss.

Note

Removing the meter batteries will not affect your stored result. However, you may need to reset your meter settings. See pages 12 ~ 15.

UNDERSTANDING ERROR AND OTHER MESSAGES

MESSAGE	WHAT IT MEANS	WHAT TO DO
Er l	A used test strip was inserted.	Repeat the test with a new test strip.
8-3	The blood or control solution sample was applied before the ••••••••••••••••••••••••••••••••••••	Repeat the test with a new test strip and wait until the ••••••• symbol appears before applying the blood or control solution sample.
8-3	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range (10 ~ 40°C / 50 ~ 104°F) and repeat the test after the meter and test strips have reached a temperature within the operating range.

MESSAGE	WHAT IT MEANS	WHAT TO DO
Er 4	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test after inserting a new test strip.
8r 5	This error message may appear when the wrong blood glucose test strip is used instead of <i>Bravo</i> [™] blood glucose test strip.	Repeat test after inserting a Bravo™ test strip.
8r8	There is a problem with the meter.	Do not use the meter. Contact your authorized <i>Endomedical</i> ™ sales representative.



If the error messages persist, contact your authorized *Endomedical*™ sales representative.

GENERAL TROUBLESHOOTING

PROBLEM	TROUBLESHOOTING
The display is blank even after inserting a test strip.	 Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely into the test strip port. Check if the appropriate test strip was used. Check whether the batteries are inserted with the '+' side facing up. Replace the batteries.
The test does not start even after apply- ing the blood sample on the strip.	 Check if the confirmation window is filled completely. Repeat the test after inserting a new test strip.
The test result does not match the way you feel.	 Repeat the test after inserting a new test strip. Check the expiration date of the test strip. Check if the strip has passed the discard date (date of opening the test strip vial plus 6 months). Check the meter.

PERFORMANCE CHARACTERISTICS

The performance of *Bravo*[™] Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the **Bravo™** BGM System (Model GM505MA, GM505MB, GM505MC, GM505MD, GM505ME) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by diabetic patients at clinic centers.

).97
).13 mmol/L
.993
14
.5–32.5 mmol/L

Accuracy results for glucose concentration < 4.2 mmol/L

Within ± 0.28 mmol/L	Within \pm 0.56 mmol/L	Within \pm 0.83 mmol/L
8/8 (100%)	8/8 (100%)	8/8 (100%)

Accuracy results for glucose concentration \geq 4.2 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
49/106 (46%)	82/106 (77%)	101/106 (95%)	106/106 (100%)



If the problem is not resolved, please contact your authorized *Endomedical*[™] sales representative

PRECISION

Precision: The precision studies were performed in a laboratory using *Bravo*[™] BGM Systems.

Within Run Precision

*Blood avg.	2.8 mmol/L	SD = 0.1 mmo/L
*Blood avg.	5.1 mmol/L	SD = 0.2 mmo/L
*Blood avg.	7.8 mmol/L	CV = 2.4%
*Blood avg.	11.3 mmol/L	CV = 2.9%
*Blood avg.	19.2 mmol/L	CV = 2.9%

Total Precision

*Control avg.	2.6 mmol/L	SD = 0.1 mmol/L
*Control avg.	7.6 mmol/L	CV = 3.1%
*Control avg.	18.7 mmol/L	CV = 3.5%

This study shows that there could be variation of up to 3.5%.

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