embecta

emVia™ Pro

Blood Glucose Monitoring System

User Manual

Table of Contents

PGUAA-0000616 REV0 2025-02

01 Important Information: Read This First!

For optimum safety and benefits, please read the entire manual contents before using the system.

Intended purpose:
The emVia Pro Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use). The system is intended for self-testing as an aid in monitoring the effectiveness of diabetes control for individuals with diabetes mellitus or prediabetes to quantitatively measure glucose in fresh capillary whole blood from the fingertip. In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose when drawn by trained healthcare professionals. The system shall not be used for the diagnosis of or screening for diabetes.

Meaning of symbols used:

IVD In vitro diagnostic medical device	Temperature limit
Caution	Manufacturer
Biological risks	Importer
Do not re-use	LOT Batch code
Consult instructions for use	Direct current
WEEE (waste electrical and electronic equipment)	Device for self-testing

- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The emVia Pro Blood Glucose Meter detects this electrical current and measures the amount of glucose in the blood sample.
- The emVia Pro Blood Glucose Meter is designed to minimise code related errors in monitoring by using the no-coding function.
- The emVia Pro Blood Glucose Meter should only be used with emVia Pro Blood Glucose Test Strips.

- An abnormally high or low red blood cell count (hematocrit level over 70 % or below 15 %) may produce inaccurate results.
- If your blood glucose test result is below 60 mg/dL or above 240 mg/dL, consult a healthcare professional immediately.
- Inaccurate blood glucose results may occur in severely hypotensive individuals or patients in shock. Inaccurate low blood glucose results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.

If you need assistance, please contact your authorised sales representative or visit embecta.com for more information.

02 Specifications

Product specifications

Measurement range	10–600 mg/dL
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	• Fresh capillary whole blood (fingertip) • Venous whole blood* • Arterial whole blood* • Neonatal capillary whole blood (heelstick)* * healthcare professional only
Model	GM01YAA
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	2,000 tests
Power	One 3.0 V lithium battery (disposable, type CR2032)
Memory	1,000 test results
Size	95 x 49.6 x 17.9 mm
Weight	52 g (with battery)

Operating ranges

Temperature	5–45 °C
Hematocrit	15–70 %
Relative humidity	10–90 %

Storage/Transport conditions

Temperature	Meter (with battery)	0–50 °C
	Test strip	1–30 °C
	Control solution	8–30 °C
Relative humidity	Test strip	10–90 %

03 System Components

The SKU numbers vary depending on the emVia Pro Blood Glucose Monitoring System's components. Check the SKU number indicated on the product box to identify the components in the table below.

SKU	Components
328670	• emVia Pro Blood Glucose Meter (GM01YAA) • Battery (1) • Instructions for Use • Carrying Case
328668	• emVia Pro Blood Glucose Meter (GM01YAA) • emVia Pro Blood Glucose Test Strips (10) • Battery (1) • Instructions for Use • Carrying Case

Note
- Check all the components after opening the emVia Pro Blood Glucose Monitoring System package.
- The following items can be purchased separately. Please contact your authorised sales representative or the retailer you purchased the products.
  – emVia Pro Blood Glucose Test Strips (50, 25 and 10 strips)
  – emVia Glucose Control Solutions

04 Inserting or Replacing the Battery

The emVia Pro Blood Glucose Meter uses one 3.0 V lithium battery. Before using the meter, check the battery compartment and insert a battery if empty. When the – + symbol appears on the display while the meter is in use, the battery should be replaced as soon as possible. The test results may not be saved if the battery runs out.

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

Step 2
Remove the used battery. Slip your index finger under the battery to lift and pull out as shown. Insert a new battery with the + side facing up and make sure the battery is inserted firmly.

Step 3
Place the cover on the battery compartment. Push it down until you hear the tab click into place.

Note
Removing the meter battery will not affect your stored results. However you may need to reset your meter settings. See page 12.

05 Caring for Your System

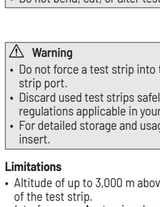
Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol. Do not use organic solvents such as benzene or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.

Caution
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time. It is recommended to store and use the test system indoors.
- 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 shock.
- Do not try to fix or alter the meter in any way.
- Store all the meter components in the carrying case to prevent loss and help keep the meter clean.
- Avoid getting any liquid or moisture in the test strip vial or foil packet. This can affect the test strips and cause inaccurate test results.
- Do not apply samples other than capillary, venous, neonatal, or arterial whole blood or control solution to the test strip.
- Store the meter in a cool and dry place between 0–50 °C.
- In the event of any serious incident with the emVia Pro Blood Glucose Monitoring System, please report to manufacturer and the competent authority of the Member State.

Disposal of the meter
If you need to throw your meter away, you should follow existing policies and procedures of your own country or region.
For information about correct disposal, please contact your local council or authority. If you need assistance, contact your authorised embecta sales representative or visit embecta.com.

06 emVia Pro Blood Glucose Test Strip

The emVia Pro Blood Glucose Monitoring System measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the sample inlet of the strip.



Contact bars
Gently push the test strip, with its contact bars facing up, into the test strip port of meter

Confirmation window
Check here to see whether sufficient blood sample has been applied

Sample inlet to apply blood sample
Apply blood sample here for testing

Warning
- The emVia Pro Blood Glucose Test Strips should be used with fresh capillary whole blood samples immediately after drawn, or with neonatal heelstick capillary, venous, and arterial whole blood samples within 30 minutes after drawn. Venous, neonatal, and arterial whole blood samples should be drawn by healthcare professionals. Besides whole blood samples, serum or plasma samples can affect test results.
- Venous and arterial whole blood specimens containing the anticoagulants EDTA and Heparin are acceptable. Iodoacetate or fluoride/oxalate should not be used.
- Heel stick neonatal capillary whole blood specimens containing the anticoagulants EDTA and Heparin are acceptable. The system is not for testing neonatal cord blood samples.
- Do not reuse test strips.
- Use all of the test strips within the expiration date printed on the test strip box and vial label or foil packet.
- Dispose of test strips past the expiration or discard date immediately. Using test strips past their expiration or discard date can produce incorrect test results.
- Test strips in both unopened and opened vials, and unopened foil packet can be used up until the expiration date printed on the test strip box and vial label or foil packet if the test strips are used and stored according to its storage and handling methods.
- Store the vial or foil packet in a cool and dry place between 1–30 °C and 10–90 % relative humidity. Do not freeze.
- Keep the vial or foil packet of test strips away from direct sunlight or heat.
- Store unused test strips in their original vial or foil packet to avoid damage or contamination.
- Store test strips only in their original vial.
- Push the cap down on the vial immediately after taking out a test strip to fully close the vial and maintain air tightness.
- Use the test strip immediately after taking it out of the vial or foil packet.
- Avoid getting any liquid or moisture in the test strip vial or foil packet. This can affect the test strips and cause inaccurate test results.
- Do not apply samples other than capillary, venous, neonatal, or arterial whole blood or control solution to the test strip.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.

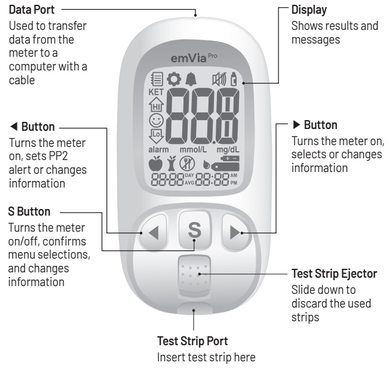
Warning
- Do not force a test strip into the meter. Gently push it into the meter's test strip port.
- Discard used test strips safely in appropriate containers according to the regulations applicable in your country.
- For detailed storage and usage information, refer to the test strip package insert.

Limitations
- Altitude of up to 3,000 m above sea level has no effect on the performance of the test strip.
- *Interferences*: Acetaminophen, ascorbic acid (vitamin C), uric acid and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate high results.
- Do not use during or within 24 hours of receiving xylose absorption testing as it may cause inaccurate results.

Chemical composition
Each emVia Pro Blood Glucose Test Strip contains the following reagents:
- Glucose dehydrogenase (FAD-dependent): 3.1 units
- Hexaammineruthenium(III) chloride: 7.8 µg
- Thionine acetate: 0.7 µg

Caution
- Use only the meters that are compatible with the test strips, otherwise it may lead to an error message.
- Keep the test strips, test strip vial, and test strip box away from children. There is a choking hazard from the test strips, foil packet and vial cap when swallowed. Drying agents in the vial cap may be harmful if inhaled or swallowed, and may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse.
- If the test strip does not absorb the blood sample properly, please contact your authorised sales representative.

07 emVia Pro Blood Glucose Meter



Note
The unit of measurement is fixed and it cannot be changed by the user.

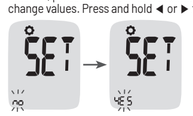
08 emVia Pro Blood Glucose Meter Display

① **Memory symbol:** appears when test results stored in the memory are displayed
② **Setting symbol:** appears when in SET mode
③ **PP2 alert:** appears when the post-meal alert has been set
④ **Mute symbol:** appears only when the sound is set to OFF
⑤ **Control Solution flag:** indicates that the meter is in Control Solution Test Mode and appears when the control solution test results are saved or displayed
⑥ **Test results:** test results displaying panel
⑦ **Decimal point:** appears when the blood glucose measuring unit is set to mmol/L
⑧ **KET:** appears when the test result is higher than 240 mg/dL
⑨ **Hi symbol:** appears when the test result is higher than the selected hyperglycemia level
⑩ **Smile symbol:** appears when the test result is within the selected normal blood glucose range
⑪ **Lo symbol:** appears when the test result is lower than the selected hypoglycemia level
⑫ **alarm:** appears when the time alarm has been set
⑬ **mmol/L, mg/dL:** unit for blood glucose
⑭ **Battery symbol:** indicates meter battery is running low and needs to be replaced
⑮ **Blood insertion symbol:** indicates meter is ready for the application of a drop of blood or control solution
⑯ **Fasting test flag:** used for tests done after fasting for at least 8 hours
⑰ **Post-meal test flag:** used for tests done after eating
⑱ **Pre-meal test flag:** used for tests done before eating
⑲ **Month/Day/Hour/Minute:** appears date and time

Note
It is recommended to check if the display screen on the meter matches the illustration above every time the meter turns on. Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

09 Setting Up Your System

Press and hold **S** for 3 seconds to enter the SET Mode. After all settings are finished, press and hold **S** for 3 seconds to turn off the meter. Press ◄ or ► to change values. Press and hold ◄ or ► to scroll faster.



Step 1 Entering SET Mode
Press and hold **S** for 3 seconds to enter the SET Mode. After all the segments flash across the screen, the 'SET' will show up. Press ◄ or ► to select 'YES' and press **S** to go to the next step.

Adjusting the Date and Time

Step 2 Setting the Year
Press ◄ or ► to adjust until the correct year appears. When the present year appears, press **S** to confirm your selection and to go to the next step.

Step 3 Setting the Month
A number indicating the month will blink on the screen.
Press ◄ or ► until the correct month appears.
Press **S** to confirm your selection and to go to the next step.

Step 4 Setting the Date
Press ◄ or ► until the screen displays the correct date. Press **S** to confirm the date and to go to the next step.

Step 5 Setting the Time Format
The meter can be set in the AM/PM 12-hour or the 24-hour clock format.
Press ◄ or ► to select a format. The AM•PM symbol is not displayed in the 24-hour format.
After selecting the format, press **S** to go to the next step.

Step 6 Setting the Hour
Press ◄ or ► until the correct hour appears.
After the hour is set, press **S** to go to the next step.

Step 7 Setting the Minute
Press ◄ or ► until the correct minute appears.
After setting the minute, press **S** to go to the next step.

Setting the Sound On/OFF

Step 8
On pressing ◄ or ►, the screen will display 'On' or 'OFF'. Press **S** to confirm the selection.
The meter will beep in the following instances if set to On:
- When you push a button to turn on the meter,
- 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 press and hold ◄ to set the post-meal (PP2) alert,
- When it is time for a pre-set blood glucose test.

If the sound is set to OFF, none of the sound functions will work. After setting the sound, press **S** to go to the next step.

Note
The 🔕 symbol is displayed only when the sound is set to OFF.

Turning on the Strip Expiration Date Indicator

Step 9
This mode allows you to turn the strip expiration date indicator on or off. This mode turns the function on or off only. See page 16 to set the strip expiration date.
When 'EP' appears on the screen, press ◄ or ►. The screen will display 'On' or 'OFF'. Press **S** to confirm the setting.
If you do not want to set the indicator, press **S** while the screen displays 'OFF'.

Note
If the pre-set expiration date expires, the meter will display 'EP' when the test strip is inserted. 'EP' shows alternately also when the test result is displayed right after the test.
If the expiration date is set to October of 2026, the meter will display 'EP' at the start of October, 2026.

Setting the Hypoglycemia (Lo) Indicator

Step 10
This mode allows you to select the desired level for the hypoglycemia indicator (possible low blood sugar). You will be alerted any time your test result is lower than the selected level. Press ◄ or ► until the desired hypoglycemia level between 10–90 mg/dL appears.
Press **S** to confirm the hypoglycemia level and to go to the next step.

Note
If the test result is lower than the pre-set hypoglycemia level, the meter will display the following.

Caution
Ask your healthcare professional to help you decide what your hypoglycemia level is before setting your level.

Setting the Hyperglycemia (Hi) Indicator

Step 11
This mode allows you to select the desired level for the hyperglycemia indicator (possible high blood sugar). You will be alerted any time your test result is higher than the selected level.
Press ◄ or ► until the desired hyperglycemia level between 120–349 mg/dL appears. Press and hold **S** to confirm the hyperglycemia level and turn the meter off.

Note
If the test result is higher than the pre-set hyperglycemia level, the meter will display 🏠 along with the measurement value. 'KET' will blink 3 times when the result is between 241–600 mg/dL.

Note
- If your blood glucose is measured to be more than 240 mg/dL, you may also have ketones.
- The emVia Pro meter is not intended to detect ketones.
- If you see 'KET' displayed on your meter, ask your healthcare professional when and how you should test for ketones.

Caution
Ask your healthcare professional to help you decide what your hyperglycemia level is before setting your level.

Note
If the test result is within the selected normal blood glucose range, the smile symbol will be displayed as shown.

10 Setting the Strip Expiration Date Indicator

Step 1 Entering the Expiration Date Setting
Press and hold ◄ and ► at the same time for 3 seconds to enter the expiration date settings. After all segments flash across the screen, 'EP' will show up.

Note
The strip expiration date is printed on the emVia Pro test strip box or vial label.

Step 2 Setting the Year
A number indicating the year will blink in the left corner of the screen. Press ◄ or ► until the correct year appears. Press **S** to confirm the year and set the month.

Step 3 Setting the Month
A number indicating the month will blink at the bottom of the screen. Press ◄ or ► until the correct month appears. Press and hold **S** for 3 seconds to confirm the month and turn off the meter.

11 Checking the System

You may check your meter and emVia Pro test strips using the emVia Control Solution.
The emVia Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly. The emVia Pro test strip vials have emVia Control Solution ranges printed on their labels. Compare the result displayed on the meter to the control solution range printed on the test strip vial or box. Before using a new meter or a new vial of test strips, you may conduct a control solution test following the procedure on pages 18–20.

Note
- Use the emVia Control Solutions only with their corresponding test strips. The control solutions are available for purchase separately.
- Use before the expiration date shown on the bottle and within 3 months (90 days) of opening.
- Discard expired control solution safely in appropriate containers according to the regulations applicable in your country.
- 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) before testing to obtain correct results.
- Do not refrigerate or freeze the control solution.
- 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 between 8–30 °C.
- Do not swallow or inject the control solution.
- The control solutions contain a dye that may stain clothes.

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 or a new box 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

Step 1 Inserting Test Strip
Insert a test strip into the meter's test strip port, with the contact bars facing upwards. Gently push the test strip into the port until the meter beeps. Be careful not to bend the strip while pushing it in.
The – + symbol will show up.

Step 2 Activating Control Solution Test Mode
Press and hold ▶ for 3 seconds to activate the Control Solution Test Mode. This will also flag the control solution test result. To undo the control solution flag, press and hold ▶ for another 3 seconds.

Note
If control solution testing is performed without the control solution flag, an Er8 message may appear or the results may fall outside the range printed on the test strip vial.

Step 3 Applying Control Solution to Test Strip
Shake the 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.
Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown.
After the symbol appears on the display, apply the solution to the sample inlet of the test strip until the meter beeps. Make sure the confirmation window fills completely.

Note
The meter may switch off if the control solution sample is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 1.

Step 4 Waiting for the Result
The display segments will rotate clockwise and a test result will appear after the meter counts down from 5 to 1.
The test result with control solution flag is stored in the memory but not included in the averages.

emVia Control Solution Range
Control L : XX-XX mg/dL X.X-X.X mmol/L
Control H : XX-XX mg/dL X.X-X.X mmol/L

Step 5 Comparing the Result
Compare the result displayed on the meter to the range printed on the test strip vial or box. The result should fall within the range.

Caution
The range printed on the test strip vial or box is for the Control Solution only. It has nothing to do with your blood glucose levels.

Note
Please request from your Healthcare Provider in your region.

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 or on the test strip box.
Repeat the control solution test if the test result falls outside of the range.
Out of range results may occur in following situations:

Situations	Do This
• When the control solutions are not used with their corresponding test strips, • 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 **Note** 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, • 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, the test strip and meter may not be working properly. Do not use your system and contact sales representative.

12 Using the Lancing Device

You will need a lancing device in order to collect a blood sample.
Before testing, prepare a lancet and a lancing device according to the instructions enclosed with the products. emVia Pro Blood Glucose Monitoring System does not come with lancet and lancing device, you may use any brand of lancet and lancing devices that are registered in your region. Please follow the instruction supplied together with the purchased lancet and lancing device or you may follow the below guide as reference.
- The lancing device is for use by a single user only and should not be shared with anyone.
- 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.

Caution
To avoid infection when drawing a sample, do not use a lancet more than once, and:
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

Note
- Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.
- 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 to get an adequate sample size.

13 Blood Glucose Testing

Preparing the Meter and Test Strip

Step 1
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The symbol will appear on the screen.

Applying Blood Sample

Step 2
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. You need a minimum volume of 0.5 microliter for blood glucose test with emVia Pro test strip (actual size of 0.5 µL: ●).

Step 3
After the symbol appears on the screen, apply the blood sample to the sample inlet of the test strip till the meter beeps. If the confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear. It is recommended to place the test strip vertically into the blood sample site as shown below.

Caution
Do not allow any foreign substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.
- Do not apply the blood sample directly to the test strip port.
- Do not apply the blood sample to the test strip while holding the meter in a way that the tip of the test strip faces upwards.
  The blood sample may run down the surface of the test strip and flow into the test strip port.
- Do not store your meter in unsanitary or contaminated sites.

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

Step 4
At this time, the display segments will rotate clockwise while the blood is going in. Blood glucose test results 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.

Blood glucose test result

Step 5
You can attach a flag to a blood glucose test result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press ◀ or ▶ to select a pre-meal flag ( ), a post-meal flag ( ), or a fasting flag ( ). When you remove the test strip while the desired flag is blinking, the test result is stored with the flag.
If you do not want to add any flags on the test result, remove the strip after the test result is displayed.

No flag | Pre-meal flag | Post-meal flag | Fasting flag

Discarding Used Lancets
emVia Pro Blood Glucose Monitoring System does not come with lancet and lancing device, you may use any brand of lancet and lancing devices that are registered in your region. Please follow the instruction supplied together with the purchased lancet and lancing device or you may follow the below guidance as reference.

Step 1
Unscrew the lancing device tip.

Step 2
Stick the lancet into the saved protective disk.
Push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.

Caution
- The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.
- When disposing of the used lancets, you should follow existing policies and procedures of your own country or region. For information about correct disposal, please contact your local council or authority.

14 HI and Lo Messages

HI Message
The meter displays blood glucose results between 10–600 mg/dL. 'HI' appears when the blood glucose level is higher than 600 mg/dL and indicates severe hyperglycemia (much higher than normal glucose levels).
If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

Lo Message
'Lo' appears when a blood glucose test result is lower than 10 mg/dL and indicates severe hypoglycemia (very low glucose levels).
If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.

Note
Please contact your authorised sales representative if such messages are displayed even though you do not have hyperglycemia or hypoglycemia.

15 Target Blood Glucose Ranges

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

Expected Results
Normal blood glucose levels for an adult without diabetes are below 100 mg/dL before meals and fasting* and are lower than 140 mg/dL two hours after meals.
*Fasting is defined as no caloric intake for at least eight hours.

Unexpected Results
Low or high blood glucose readings can indicate a potentially serious medical condition. If your results are unusually high or low, or do not match the way you feel, repeat the test with a new test strip. If your reading is inconsistent with your symptoms or your result is lower than 60 mg/dL or higher than 240 mg/dL, contact your healthcare professional.

Reference
American Diabetes Association (Standards of Medical Care in Diabetes – 2021. *Diabetes Care*), January 2021, vol. 44 (Supplement 1): S15-S33.

16 Transferring Test Results Using Cable

Test results stored in emVia Pro meter can be transferred from the meter to a computer using SmartLog software and cable. The meter screen displays 'PC' when it is connected to the computer using the data cable. You are responsible for properly securing and managing your PC. If you suspect an adverse cybersecurity event related to emVia Pro meter, contact your authorised embecta sales representative or visit *embecta.com*.

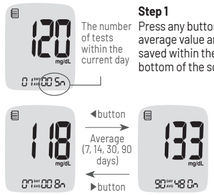
Note
- Please note that this kit does not come with the cable and embecta does not supply the cable.
- Please note that SmartLog stores sensitive health-related information on your PC. We recommend keeping your PC up-to-date with the latest security software. For more information on keeping your PC and information safe, please contact the manufacturer of your PC.

17 Meter Memory

The emVia Pro meter can save up to 1,000 test results with time and date. Test results are stored in the measured order regardless of set time or date on the meter. If the memory is full, the oldest test result will be deleted and the latest test result will be stored. The meter only calculates and displays the averages of blood glucose test results by total test results, pre-meal test results ( ),

post-meal test results ( ), and fasting test results ( ) from the last 1, 7, 14, 30 and 90 days.

Viewing Averages Stored in Memory



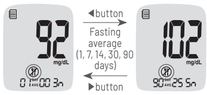
The number of tests within the current day

Step 1
Press any button to turn the meter on. The 1 day average value and the number of the test results saved within the current day will be displayed at the bottom of the screen.

Step 2 Viewing Averages
Press ◀ to view 7, 14, 30 and 90-day average values and the number of tests performed for the last test period.

Step 3 Viewing Pre-meal Averages
Repeatedly press ◀ to view 1, 7, 14, 30 and 90-day average values and the number of tests performed pre-meals with the symbol for the last test period.

Step 4 Viewing Post-meal Averages
Press ◀ to view 1, 7, 14, 30 and 90-day average values and the number of tests performed post-meals with the symbol for the last test period.

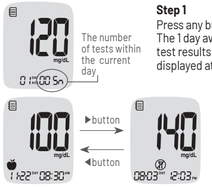


Step 5 Viewing Fasting Averages
Press ◀ to view 1, 7, 14, 30 and 90-day average values and the number of tests performed during fasting with the symbol for the last test period.

Step 6
Use ▶ to scroll back through the averages seen previously.
Press **S** to turn off the meter.

Note
The control solution test results saved with the symbol are not included in the averages.

Viewing Test Results Stored in Memory



The number of tests within the current day

Step 1
Press any button to turn the meter on.
The 1 day average value and the number of the test results saved within the current day will be displayed at the bottom of the screen.

Step 2
Use ▶ to scroll through the test results, starting from the most recent and ending with the oldest. Press ◀ to return to the results seen previously.

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

Note
The control solution test results saved with the symbol will be displayed with the symbol when you review the stored test results.

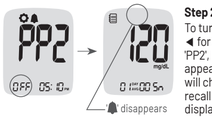
18 Setting the Alarm Function

Four types of alarms can be set in the emVia Pro meter: one post-meal alert (PP2 alert) and three time set alarms (alarm 1–3). The PP2 alert goes off 2 hours after setting the alert. The alarms ring for 15 seconds and can be silenced by pressing any button or by inserting a test strip.

Setting the Post-meal Alert (PP2 alert)

Step 1 Turning the PP2 alert On
Without inserting a test strip, press and hold ◀ for 3 seconds to set the post-meal alert.
'PP2', bell ( ) symbol and 'On' will be displayed. The screen will then automatically change to the memory recall mode.
At this time, bell ( ) symbol, indicating that the PP2 alert has been set, will be displayed on the screen.

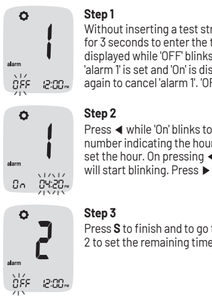
Note
The PP2 alert will automatically turn off if the meter's time setting is adjusted to more than two hours before or just past the currently activated PP2 alert time.



disappears

Step 2 Turning the PP2 alert OFF
To turn off the PP2 alert, press and hold ◀ for 3 seconds.
'PP2', bell ( ) symbol and 'OFF' will appear on the screen. Then the screen will change automatically to the memory recall mode without bell ( ) symbol displayed.

Setting the Time Alarms (alarm 1–3)



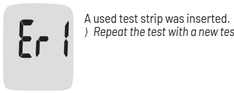
Step 1
Without inserting a test strip, press ◀ and **S** simultaneously for 3 seconds to enter the time alarm mode. 'alarm 1' will be displayed while 'OFF' blinks on the screen. On pressing ▶, 'alarm 1' is set and 'On' is displayed on the screen. Press ▶ again to cancel 'alarm 1'. 'OFF' will blink on the screen.

Step 2
Press ◀ while 'On' blinks to adjust the time of 'alarm 1'. A number indicating the hour will blink on the screen. Press ▶ to set the hour. On pressing ◀, the number indicating the minute will start blinking. Press ▶ to set the minute.

Step 3
Press **S** to finish and to go to 'alarm 2' mode. Repeat steps 1 to 2 to set the remaining time alarms (alarm 2–3).

Step 4
Press and hold **S** for 3 seconds to finish and turn the meter off.

19 Understanding Error Messages



A used test strip was inserted.
› *Repeat the test with a new test strip.*

The blood or control solution sample was applied before the symbol appeared.
› *Repeat the test with a new test strip and wait until the symbol appears before applying the blood or control solution sample.*

The temperature during the test was above or below the operating range.
› *Move to an area where the temperature is within the operating range (5–45 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.*

The blood sample has abnormally high viscosity or insufficient volume.
› *Repeat the test with a new test strip.*

This error message may appear when the wrong blood glucose test strip is used instead of emVia Pro test strip.
› *Repeat the test with a emVia Pro test strip.*

There is a problem with the meter.
› *Do not use the meter.*
Contact your authorised sales representative.

An electronic error occurred during the test, commonly caused by foreign materials in the meter port (e.g., blood, dirt, dust), and/or physical damage to the meter or strips due to incorrect use or storage.
› *Repeat the test with a new test strip. If the error message persists, contact your authorised sales representative.*

Note
If the error messages persist, contact your authorised embecta sales representative.

20 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 battery is inserted with the + side facing up. • Replace the battery.
The test does not start even after applying 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 or discard date of the test strip. • Perform control solution test.

Note
If the problem is not resolved, please contact your authorised embecta sales representative.

21 Performance Characteristics

System Accuracy and Measurement Precision
The performance of emVia Pro Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.
Accuracy: The accuracy of the emVia Pro Blood Glucose Monitoring System using the YSI Model 2300 Glucose Analyzer (laboratory instrument) as the comparator method are described below. The results are calibrated to be equivalent to plasma glucose concentrations.
The following results were obtained by diabetic patients at clinic centers.
- For self-testing
  — Fresh capillary whole blood

Slope	1.00	Number of tests	600
Y-intercept	5.60 mg/dL	Range tested	35–453 mg/dL
Correlation coefficient (r)		1.00	

System accuracy results for glucose concentration < 100 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
100/174 (57.5 %)	165/174 (94.8 %)	173/174 (99.4 %)

System accuracy results for glucose concentration ≥ 100 mg/dL

Within ±5 %	Within ±10 %	Within ±15 %
206/426 (48.4 %)	385/426 (90.4 %)	420/426 (98.6 %)

System accuracy results for glucose concentrations between 35 mg/dL and 453 mg/dL

Within ±15 mg/dL and Within ±15 %	593/600 (98.8 %)

- For professional use
  — Venous whole blood
  System accuracy results for glucose concentrations between 33.7 mg/dL and 497.3 mg/dL

Within ±15 mg/dL and Within ±15 %	591/600 (98.5 %)

  — Arterial whole blood
  System accuracy results for glucose concentrations between 27.7 mg/dL and 456.0 mg/dL

Within ±15 mg/dL and Within ±15 %	600/600 (100 %)

  — Neonatal capillary whole blood
  System accuracy results for glucose concentrations between 26.1 mg/dL and 366.3 mg/dL

Within ±15 mg/dL and Within ±15 %	629/630 (99.8 %)

Precision: The precision studies were performed in a laboratory using emVia Pro Blood Glucose Monitoring Systems.

Within Run Precision			*Between Run Precision*		
Blood average	38 mg/dL	SD = 2.0 mg/dL	Control average	35 mg/dL	SD = 1.5 mg/dL
	83 mg/dL	SD = 3.6 mg/dL		120 mg/dL	CV = 4.0 %
	130 mg/dL	CV = 3.2 %		347 mg/dL	CV = 4.1 %
	192 mg/dL	CV = 2.8 %			
	312 mg/dL	CV = 2.5 %			

This study shows that there could be variation of up to 4.1 %.

Measurement Range
The claimed linear range of 10–600 mg/dL has been verified.

Influence Quantities

Packed Cell Volume (Hematocrit)
Packed cell volume evaluation was conducted in various hematocrit levels. The range of hematocrit levels within the acceptance criteria is 15–70 %.

Interferences
The effect of various interfering substances was evaluated in whole blood samples. The presence of the following substances within the given concentrations does not affect blood glucose measurements. Higher concentrations of the substances shown below may cause inaccurate blood glucose results.

No.	Interferent	Concentration	No.	Interferent	Concentration
1	Acetaminophen (paracetamol)	20 mg/dL	13	Heparin	330 U/dL
2	Ascorbic acid	6 mg/dL	14	Ibuprofen	50 mg/dL
3	Bilirubin (conjugated)	50 mg/dL	15	Icodextrin	1,095 mg/dL
4	Bilirubin (unconjugated)	40 mg/dL	16	L-Dopa	0.75 mg/dL
5	Cholesterol	500 mg/dL	17	Maltose	480 mg/dL
6	Creatinine	15 mg/dL	18	Methyldopa	2.25 mg/dL
7	Dopamine	0.1 mg/dL	19	Pralidoxime Iodide	25 mg/dL
8	EDTA	0.1 mg/dL	20	Salicylate	60 mg/dL
9	Galactose	60 mg/dL	21	Tolazamide	9 mg/dL
10	Gentisic acid	1.8 mg/dL	22	Tolbutamide	72 mg/dL
11	Glutathione (reduced)	93 mg/dL	23	Triglycerides	1,500 mg/dL
12	Hemoglobin	1,000 mg/dL	24	Uric acid	23.5 mg/dL
			25	Xylose	12.4 mg/dL

Compounds of xylose ≥ 12.4 mg/dL at glucose concentrations of 50–100 mg/dL may cause overestimation of blood glucose results.

User Performance Evaluation
A study evaluating glucose values from fingertip capillary blood samples obtained by 102 lay persons showed the following results: 100 % within ±15 mg/dL of the medical laboratory values at glucose concentrations below 100 mg/dL, and 97.5 % within ±15 % of the medical laboratory values at glucose concentrations at or above 100 mg/dL.

Metrological Traceability
The system has been evaluated using the YSI glucose analyzer as the reference method and traceable to the NIST Standard Reference Material (SRM) 917d. Using the traceability chain, the results obtained with test strips for control solutions can also be traced back to the NIST standard.

22 Warranty Information

Manufacturer's Warranty
embecta, Inc. warrants that the emVia Pro meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use.

The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.
embecta will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, embecta will not reimburse the consumer's purchase price.

Obtaining Warranty Service
To obtain warranty service, you must return the defective meter or meter part along with proof of purchase to your nearest sales representative.

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IVD