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Important Information: Read This First!

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

Intended Use:

The GlucoCheck Multi-Patient Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for use outside the body (*in vitro* diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

The following chart explains the symbols you'll find in the GlucoCheck Multi-Patient User Manual, product packaging, and product inserts.

IVD	*In vitro* diagnostic medical device
	Caution
	Biological risks
	Do not re-use
	Consult instructions for use
	WEEE (waste electrical and electronic equipment)
	Temperature limit
	Manufacturer
LOT	Batch code
REF	Catalogue number
SN	Serial number
	Use-by date

Important Information

- The GlucoCheck Multi-Patient Blood Glucose Monitoring System is intended for *in vitro* (outside the body) diagnostic use only.
- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The GlucoCheck Multi-Patient Blood Glucose Meter detects this electrical current and measures the amount of glucose in the blood sample.
- The GlucoCheck Multi-Patient Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The GlucoCheck Multi-Patient Blood Glucose Meter should be used only with the GlucoCheck Multi-Patient Blood Glucose Test Strips and GlucoCheck Glucose Control Solution.
- An abnormally high or low red blood cell count (hematocrit level over 65 % or below 15 %) 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.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low 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.
- Inaccurate results may occur in patients undergoing oxygen therapy.

Specifications

Product specifications

Measurement range	1.1–33.3 mmol/L
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	3,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	93 x 47 x 15 mm
Weight	51.5 g (with batteries)

Operating ranges

Temperature	5–50 °C (41–122 °F)
Relative humidity	10–90 %
Hematocrit	15–65 %

Storage/Transport conditions

Temperature	Glucose Meter (with batteries)	0–50 °C (32–122 °F)
	Test strip	1–30 °C (34–86 °F)
	Control solution	8–30 °C (46–86 °F)
Relative humidity	Test strip	10–90 %

GlucoCheck Multi-Patient Blood Glucose Monitoring System

GlucoCheck Multi-Patient Blood Glucose Monitoring System includes the following items:

* GlucoCheck Multi-Patient Blood Glucose Meter
* Owner's Booklet
* Batteries
* Carrying Case

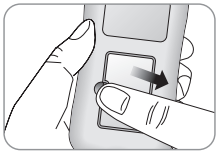
Check all the components after opening the GlucoCheck Multi-Patient Blood Glucose Monitoring System package. The exact contents are listed on the main box.

Inserting or Replacing the Batteries

The GlucoCheck Multi-Patient Blood Glucose Meter comes with two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty.
When the + – symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out completely.

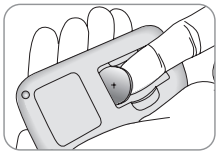
Step 1

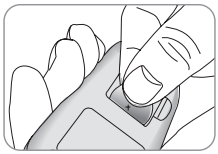
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



Step 2

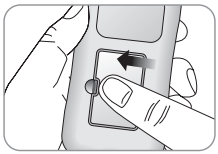
Remove the used batteries one at a time. Slip your index finger under the battery to lift and pull out as shown. Insert two new batteries with the + side facing up and make sure the batteries are inserted firmly.





Step 3

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

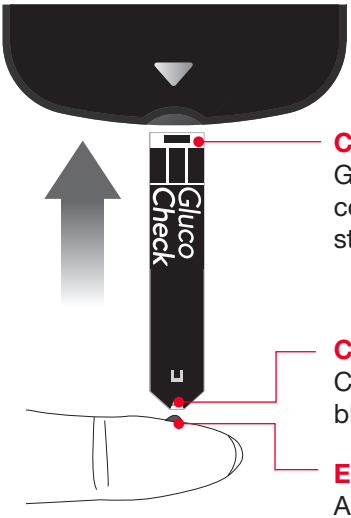


Note

Removing the meter batteries will not affect your stored result. However, you may need to reset your meter settings. See pages 17–20.

GlucoCheck Multi-Patient Blood Glucose Test Strip

The GlucoCheck Multi-Patient 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.



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.

Edge to apply blood sample
Apply blood sample here for testing.

⚠ Warning

- The GlucoCheck Multi-Patient Blood Glucose Test Strips should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiration date printed on the test strip box and vial label if the test strips are used and stored according to its storage and handling methods.
- Store test strips in a cool and dry place at a temperature of 1–30 °C (34–86 °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 GlucoCheck Multi-Patient Blood Glucose Test Strip package insert.

⚠ Caution

- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

GlucoCheck Multi-Patient Blood Glucose Meter

Display
Shows results messages.

⬆ Button
Selects or changes information.

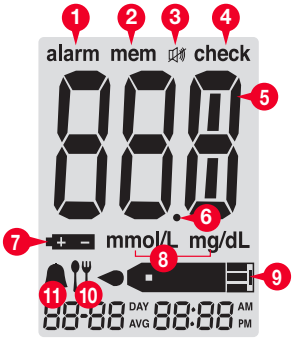
⬇ Button
Selects or changes information.

S Button
Turns the meter on/off and confirms menu selections.

Test Strip Port
Insert test strip here

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

GlucoCheck Multi-Patient Blood Glucose Meter Display



1 **alarm**	Appears when the time alarm has been set.
2 **mem**	Appears when test results stored in the memory are displayed.
3 **Mute symbol**	Appears only when the sound is set to OFF.
4 **check**	Appears when test results have not been saved.
5 **Test results**	Test results displaying panel.
6 **Decimal point**	Appears when the blood glucose measuring unit is set to mmol/L.
7 **Battery symbol**	Indicates meter battery is running low and needs to be replaced.
8 **mmol/L, mg/dL**	Unit for measuring blood glucose.

9 Blood insertion symbol	Indicates meter is ready for the application of a drop of blood or control solution.
10 Post-meal test flag	Appears during post-meal testing and when post-meal test results are displayed.
11 PP2 alert	Appears when the post-meal alert has been set.

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.

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 ⬆ or ⬇ to reach the accurate value. Press and hold ⬇ to scroll faster.

Adjusting the Date and Time

Step 1 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' will show up. Press the **S** button to go to the next step.

Step 2 Setting the Year

Press and release ⬆ or ⬇ to adjust until the correct year appears. Press and hold ⬇ button to scroll through the numbers quickly.
When the present year appears, press the **S** button to confirm your selection and to go to the next step.

Step 3 Setting the Month

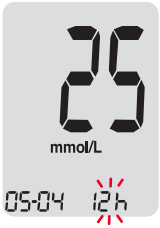
A number indicating the month will blink on the screen.
Press ⬆ or ⬇ until the correct month appears.
Press the **S** button to confirm your selection and to go to the next step.

Step 4 Setting the Date

Press ⬆ or ⬇ until the screen displays the correct date. Press the **S** button 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 the **S** button to go to the next step.



Step 6 Setting the Hour

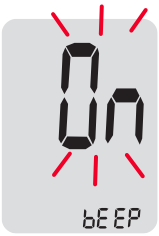
Press ⬆ or ⬇ button until the correct hour appears. After the hour is set, press the **S** button to go to the next step.

Step 7 Setting the Minute

Press ⬆ or ⬇ button until the correct minute appears. After setting the minute, press the **S** button to go to the next step.

Step 8 Setting the Sound On/OFF

On pressing ⬆ or ⬇, the screen will display the 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
- When you push the ⬆ button 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 the **S** button to go to the next step.

Note

🔇 symbol is displayed only when the sound is set to OFF.

Checking the System

You may check your meter and test strips using the GlucoCheck Blood Glucose Control Solution (control A and/or B). The GlucoCheck Blood Glucose 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 GlucoCheck Blood Glucose Control Solution ranges printed on their labels. Compare the result displayed on the meter to the GlucoCheck Blood Glucose 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 22–24.

Note

- Use only the GlucoCheck Blood Glucose 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).

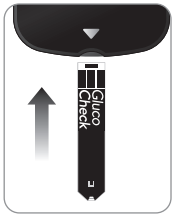
You may do a control solution test:

- 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

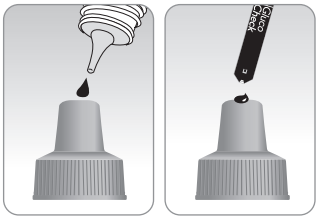
Step 1

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

Shake the 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.



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 narrow edge 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 3

The display segments will rotate clockwise on the meter display and a test result will appear after the meter counts down from 5 to 1.
After your control solution result appears on the display, press ⬇ for 3 seconds till 'check' appears on the display. When 'check' is displayed, the result is stored in the meter's memory but it is not included in the averages.

Step 4

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within the range. Used strips should be discarded safely in appropriate containers.

⚠ Caution

The range printed on the test strip vial is for the GlucoCheck Blood Glucose Control Solution only. It has nothing to do with your blood glucose level.

Comparing the Control Solution Test Results

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

Situations	Do This
• 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 21.
• 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 test strip and meter may not be working properly.

⚠ Caution

To reduce the chance of infection

Before performing a blood glucose test, observe the following safety precautions:

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases between patients and healthcare professionals.
- A new pair of clean gloves should be worn by the user before testing each patient.
- Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next patient test.
- Use only an auto-disabling, single-use lancing device for each patient.
- The meter should be cleaned and disinfected after use on each patient. See the cleaning and disinfection section on page 37–42.

For more information, please refer to the following guidelines:

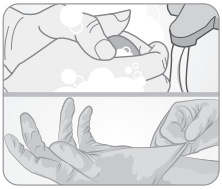
1. "Biosafety in Microbiological and Biomedical Laboratories (BMBL)", http://www.cdc.gov/biosafety/publications/bmbl5/
2. "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.
3. Canadian Biosafety Standard", https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/third-edition.html

You will need a safety lancet in order to collect a blood sample. Only an auto-disabling, single use safety lancet should be used. The auto-disabling, single use safety lancet can be purchased from an authorized distributor.

Please read the instructions provided by the manufacturer of safety lancet before using it.

Step 1

Wash hands with soap and warm water. Rinse and dry thoroughly. Disinfect sample site with alcohol prep pad. Wear appropriate protective gears such as disposable gloves.



Preparing the Meter and Test Strip

Step 2

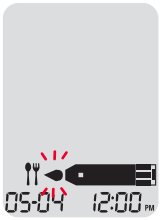
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The symbol will appear on the screen.

Flagging Post-meal Test Results

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

Step 3

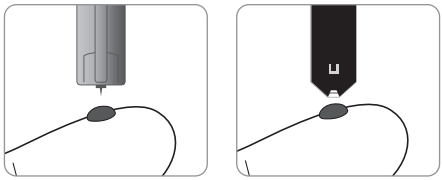
If you want to attach a post-meal flag ( ) to a test result, press and hold ⬇ for 3 seconds after inserting the test strip.
The post-meal flag ( ) and the symbol will appear on the screen. The test result will also be displayed with the post-meal flag ( ).
If you do not want to save the result as a post-meal test, move on to step 4 after step 2.



Applying Blood Sample

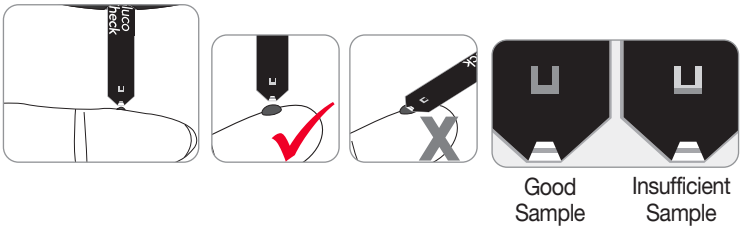
Step 4

Obtain a blood sample using a safety lancet. Place the safety lancet against the pad of the finger. The best puncture sites are on the middle or ring fingers. 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 µL: ●).



Step 5

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 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.

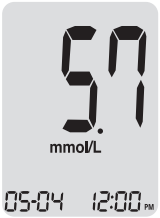


Note

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, reinsert it and start from step 2.

Step 6

Apply the blood sample to the narrow end of the test strip until you hear a 'beep'. At this time, the display segments will rotate clockwise on the meter display implying that the blood sample is being inserted.
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.



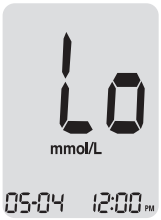
HI and Lo Messages

HI Message

The meter displays results between 1.1–33.3 mmol/L. "HI" appears when the blood glucose level is greater than 33.3 mmol/L and indicates severe hyperglycemia (much higher than normal glucose levels).
If "HI" is displayed again upon retesting, please contact the patient's healthcare provider immediately.

Lo Message

"Lo" appears when a test result is less than 1.1 mmol/L and indicates severe hypoglycemia (very low glucose levels).
If "Lo" is displayed again upon retesting, please contact the patient's healthcare provider immediately.



Target Blood Glucose Ranges

Reminders 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.	

Expected Values

A recommended target range for fasting blood glucose or glucose before meal is 4.0–7.0 mmol/L.
A recommended target range for blood glucose 2 hours after eating is 5.0–10.0 mmol/L.[1]

Reference:

1. Diabetes Canada Clinical Practice Guidelines Expert Committee, et al. (2018). Targets for glycemic control. Canadian Journal of Diabetes, 42(Suppl 1): S42–S46.

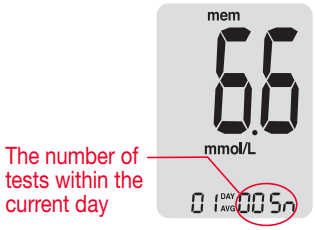
Meter Memory

The meter can save up to 1,000 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 ( ) test results from the last 1, 7, 14, 30 and 90 days.

Viewing Test Results Stored in the Meter's Memory

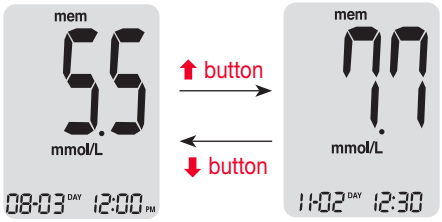
Step 1

Press the ⬆ or **S** button to turn the meter on. The current date and time will be displayed at the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.



Step 2

Use the ⬇ button 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 result, press the **S** button to turn off the meter.



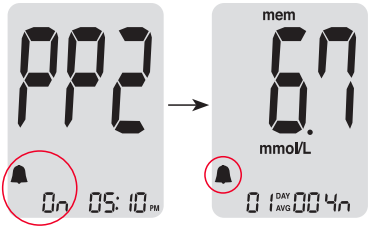
Setting the Alarm Function

Four types of alarms can be set in the 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 alarm. The alarms ring for 15 seconds and can be silenced by pressing ⬆ , ⬇ or the **S** button or by inserting a test strip.

Setting the Post-meal alert (PP2 alert)

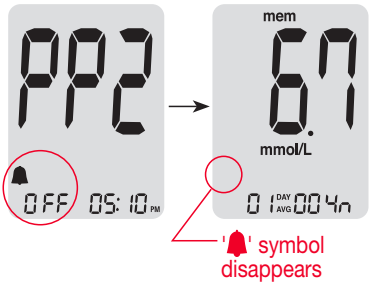
Step 1 Turning the PP2 alert On

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



Step 2 Setting the PP2 alert OFF

To turn off the PP2 alert, press and hold ⬆ for 3 seconds. "PP2", the bell (🔔) symbol and "OFF" will appear on the screen. Then the screen will change automatically to the memory check mode without bell (🔔) symbol displayed.



Setting the Time Alarms (alarm 1–3)

Step 1

Without inserting a test strip, press ⬆ and the **S** button simultaneously for 3 seconds to enter the time alarm mode. "alarm 1" will be displayed while "OFF" blinks on the screen.

Step 2

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 3

Press ⬆ to adjust the time of "alarm 1". A number representing the hour will blink on the screen. Press ⬇ to set the hour.

Step 4

On pressing ⬆ , the number indicating the minute will start blinking. Press ⬇ to set the minute.

Step 5

Press the **S** button to finish and to go to "alarm 2" mode. Repeat steps 2 to 4 to set the remaining time alarms (alarm 2–3).

Step 6

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

- To minimize the risk of transmission of blood-borne pathogens, the pre-cleaning and disinfection procedure should be performed as recommended in the instructions below.
- After disinfection, users should remove gloves and wash hands before testing the next patient.

Pre-cleaning and Disinfection:

The pre-cleaning procedure is needed to clean dirt as well as blood and other body fluids on the exterior of the meter before performing the disinfection procedure.The disinfection procedure is needed to prevent transmission of blood-borne pathogens.

- The meter should be cleaned and disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.

Note

The robustness studies were designed to simulate 3 years of multiple-patient use. We recommend cleaning and disinfecting the meter after the use on each patient. We have validated a total of 10,950 cleaning and disinfecting cycles (10,950 pre-cleaning and 10,950 disinfection cycles) to represent weekly cleaning and disinfecting over the use life of the GlucoCheck Multi-Patient Meter.
1 pre-cleaning and 1 disinfection cycles per each use * 10 uses per day * 365 days per year * 3 years = 10,950 cleaning and 10,950 disinfection cyclescycles

- We have validated Clorox Healthcare Bleach Germicidal Wipes with 0.55 % sodium hypochlorite as the active ingredient for disinfecting the GlucoCheck Multi-Patient Meter. It has been shown to be safe for use with the meter. This disinfectant is available commercially in towelette form. In addition to GlucoCheck Multi-Patient Blood Glucose Monitoring System instruction, please read the instructions provided by the manufacturer of Clorox Healthcare Bleach Germicidal Wipes before using it.

Name	Clorox Healthcare® Bleach Germicidal Wipes	
Manufacturer	Clorox® Professional Products Company Ph. 905-595-8200 www.clorox.ca	
EPA registration number	67619-12	
Active ingredients	Sodium Hypochlorite: 0.55%	

- Any disinfectant product with the EPA registration number of 67619-12 may be used on this device.
- A list of Environmental Protection Agency (EPA) registered disinfectants effective against HIV, Hepatitis C, and Hepatitis B virus can be found at the following website: http://www.epa. gov/oppad001/list_d_hepatitisbhiv.pdf

Note

The disinfectant products can be purchased through authorized distributors or by calling the Clorox® company. To find out where to purchase the disinfectant product, please contact the Clorox® company or visit their website as listed above.

Pre-cleaning and Disinfection Procedures:

1. Wear appropriate protective gears such as disposable gloves.
2. Open the cap of the Clorox Healthcare Germicidal Wipes container and pull out 1 towelette and close the cap.

3. Wipe the entire surface of the meter 3 times horizontally and 3 times vertically using one towelette to pre-clean blood and other body fluids.

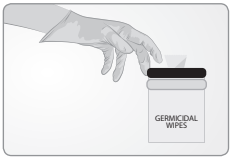
Front

Back

Both Sides

4 Dispose of the used towelette in a trash bin.

5 Pull out 1 new towelette and wipe the entire surface of the meter 3 times horizontally and 3 times vertically using a new towelette to remove bloodborne pathogens.



6 Dispose of the used towelette in a trash bin.

7 Allow exteriors to remain wet for 1 minute, then wipe the meter using a dry cloth.

8 After disinfection, the user's gloves should be removed to be thrown away and hands washed before proceeding to the next patient.

Note

Always refer to your disinfectant wipe manufacturer instructions.

Note

If any of the following deterioration signs appear after pre-cleaning or disinfecting, please stop using the system and contact your authorized sales representative.

- When the inscriptions on the exterior of the meter have been removed
- When the color of the meter has changed or faded
- When cracks or roughness develop on the meter
- When a part of the segment on the meter display does not flash
- When control solution test results do not fall within the stated range on the test strip vial

For more information, please refer to the following references:

- "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 forTransmitting Bloodborne Pathogens"(2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

⚠ Caution

- Please note only Clorox Healthcare Germicidal Wipe has been tested with GlucoCheck Multi-Patient Meter at the time of printing this manual. Contact the manufacturer or distributor for the recent updates.
- Do not get fluids inside the meter through the test strip port, data transmission port or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.

Storage and Handling Caution:

- Do not expose the meter to direct sunlight, heat, or excessive humidity 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 subject it to strong shock.
- Do not try to fix or alter the meter in any way.
- Strong electromagnetic radiation may interfere with the proper operation of this device. Keep the device away from sources of strong electromagnetic radiation, especially when measuring your blood glucose.
- Store all meter components in the carrying case to prevent loss and help keep the meter clean.

Understanding Error and Other 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– 50 °C / 41–122 °F) 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 after inserting a new test strip.*

	This error message may appear when the wrong blood glucose test strip is used instead of the GlucoCheck Multi-Patient blood glucose test strip. > *Repeat test after inserting a GlucoCheck Multi-Patient test strip.*
	There is a problem with the meter. > *Do not use the meter. Contact your authorized GlucoCheck Multi-Patient Meter sales representative.*
	An electronic error occurred during the test. > *Repeat the test with a new test strip. If the error message persists, contact your authorised GlucoCheck Multi-Patient Meter sales representative.*

Note

If the error messages persist, contact your authorized GlucoCheck Multi-Patient Meter 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 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 date of the test strip. • Perform control solution test.

Note

If the problem is not resolved, please contact your authorized GlucoCheck Multi-Patient Meter sales representative.

Performance Characteristics

The performance of GlucoCheck Multi-Patient Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the GlucoCheck Multi-Patient Blood Glucose Monitoring System 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.

Slope	0.946
Y-intercept	0.37 mmol/L
Correlation coefficient (r)	0.994
Number of samples	600
Range tested	1.6 – 27.1 mmol/L

Accuracy results for glucose concentration < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
100/186 (53.8 %)	169/186 (90.9 %)	180/186 (96.8 %)

Accuracy results for glucose concentration ≥ 5.55 mmol/L

Within ± 5 %	Within ± 10 %	Within ± 15 %
266/414 (64.3 %)	395/414 (95.4 %)	409/414 (98.8 %)

System accuracy results for glucose concentrations between 1.6 mmol/L and 27.1 mmol/L.

Within ± 0.83 mmol/L and Within ± 15 %
589/600 (98.2 %)

Precision

Precision: The precision studies were performed in a laboratory using the GlucoCheck Multi-Patient Blood Glucose Monitoring System.

Within Run Precision		
Blood average	2.1 mmol/L	SD = 0.1 mmol/L
	3.2 mmol/L	SD = 0.1 mmol/L
	6.7 mmol/L	CV = 3.6 %
	9.7 mmol/L	CV = 2.8 %
	16.8 mmol/L	CV = 3.2 %

Total Precision		
Control average	2.2 mmol/L	SD = 0.1 mmol/L
	6.7 mmol/L	CV = 3.5 %
	17.7 mmol/L	CV = 2.6 %

This study shows that there could be variation of up to 3.6 %.

Packed Cell Volume (Hematocrit)

The hematocrit levels (15–65 %) were tested to evaluate the effect of hematocrit level on measurement of glucose concentration.

Range	Average difference (Hct 15–65 %)
1.7 to 2.8 mmol/L	-0.2–0.1 mmol/L
5.3 to 8.0 mmol/L	-1.5–7.1 %
15.5 to 23.3 mmol/L	-5.4–1.1 %

Warranty Information

Manufacturer's Warranty

Innovatek Medical Inc. warrants that the GlucoCheck Multi-Patient Meter shall be free of defects in material and workmanship in normal use for a period of one (1) year. 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.

Innovatek Medical Inc. will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty.

MEMO

MEMO