⚠ WARNING:

Turn off the Bluetooth feature in areas where the use of wireless devices is restricted, such as hospitals, some healthcare professional offices, and airplanes.

Trademarks

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth® SIG, Inc. and any use of such marks by Tenovi is under license. All other trademarks and trade names are those of their respective owners.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.
This equipment should be installed and operated with minimum distance 8 inches (20 cm) between the radiator and your body.
Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate this equipment.
FCC ID: OELBM001

Note:
The SmartLog mobile app may not be compatible with all smartphones.

Table of Contents

Important Information

Intended use

The Tenovi Bluetooth Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The Tenovi Blood Glucose Monitoring System is intended for self-testing outside the body (for *in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.
The Tenovi Blood Glucose Test Strips are for use with the Tenovi Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.
The Tenovi Glucose Control Solutions are for use with the Tenovi Blood Glucose Meter and Tenovi Blood Glucose Test Strips to check that the meter and the test strips are working together properly and that the test is performed correctly.

Meaning of Symbols Used:

⚠ Cautions for safety and optimum product use

Important Safety Information

- Please use this device only for the intended use described in this User's Manual.
- Please follow the suggested cleaning and disinfection procedures described in this User's Manual.
- The Tenovi Blood Glucose Test Strips are intended for single use only. They should be disposed of in an appropriate container immediately after use.

Limitations of the Tenovi Blood Glucose Monitoring System

- An abnormally high or low red blood cell count (hematocrit level over 65 % or below 15 %) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.
- Dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional immediately.
- Altitudes of higher than 10,000 ft. (3,048 m) above sea level may have an effect on the performance of the test strip.
- The single-patient use system is for single-patient use only and should not be shared.
- Not for neonatal use.
- Do not use for diagnosis of or screening for diabetes mellitus.
- Not for use on critically ill patients.

Important Information

- The Tenovi Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use).
- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The Tenovi meter detects this electrical current and measures the amount of glucose in the blood sample.
- The Tenovi Glucose meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The Tenovi Glucose meter should be used only with Tenovi test strips.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- If your test result is below 60 mg/dL or above 240 mg/dL, consult a healthcare professional immediately.
- Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

If you need assistance, please contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST*** *. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*

This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices or long-term care facilities because it has not been cleared by the FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

Use of this device on multiple patients may lead to the transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Specifications

Product specifications	
Reported result range	20–600 mg/dL
Sample size	Minimum 0.5 µL
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	1,000 test results
Size	108.4 x 55.8 x 15 (mm)
Weight	65.5 g (with batteries)
Bluetooth®	• Frequency range: technology 2.4–2.4835 GHz • Operating range distance: maximum 32 feet (10 meters) unobstructed • Operating channels: 40 channels • Security encryption: 128-bit AES (Advanced encryption standard)

Operating ranges	
Temperature	42.8–111.2 ˚F (6–44 ˚C)
Relative humidity	10–90 %
Hematocrit	15–65 %

Storage/Transport conditions		
Temperature	Glucose Meter (with batteries)	32–122 ˚F (0–50 ˚C)
	Test strip	34–86 ˚F (1–30 ˚C)
	Control solution	46–86 ˚F (8–30 ˚C)
Relative humidity	Test strip	20–80 %

Tenovi Blood Glucose Monitoring System

The Monitoring System includes the following items:

*Tenovi Blood Glucose Meter
*User's Manual
*Quick Reference Guide
*Batteries (2)

The Monitoring System may include the following items:

*Tenovi Blood Glucose Test Strips
*Tenovi Control Solution
*Lancing Device
*Lancets
*Logbook
*Carrying Case

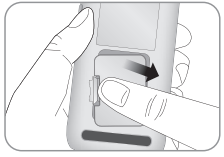
- Check all the components after opening the Tenovi Blood Glucose Monitoring System package. The exact contents are listed on the main box.
- The Tenovi Control Solutions and the cable for data management software can be ordered separately. Please contact Customer Service: ***714-418-5685 Mon–Fri, 9 am-5pm PST (Monday–Saturday)***

Inserting or Replacing the Batteries

The Tenovi Glucose meter uses 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 meter display, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out completely.

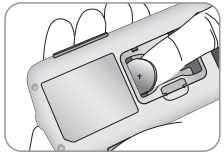
Step 1

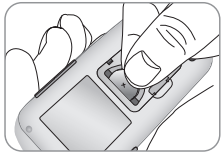
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



Step 2

Remove the old batteries one by one by lifting with the index finger and pulling it out with your thumb and index finger 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.

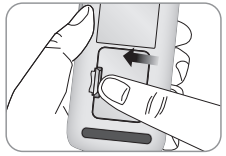




Caution:
⚠ Use only CR2032 non-rechargeable batteries.

Step 3

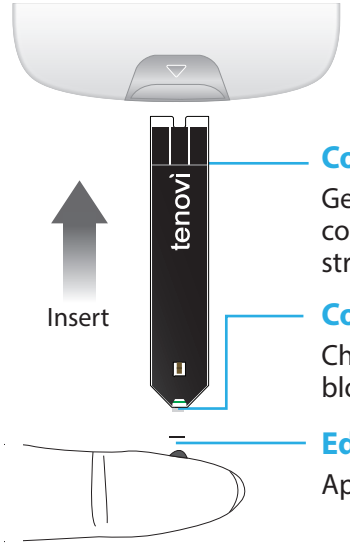
Place the cover on the battery compartment. Push down until you hear the tab click into place.



Note: Removing the meter batteries will not affect your stored results. However, you may need to reset your meter settings. See page 19.

Tenovi Blood Glucose Test Strip

The Tenovi 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

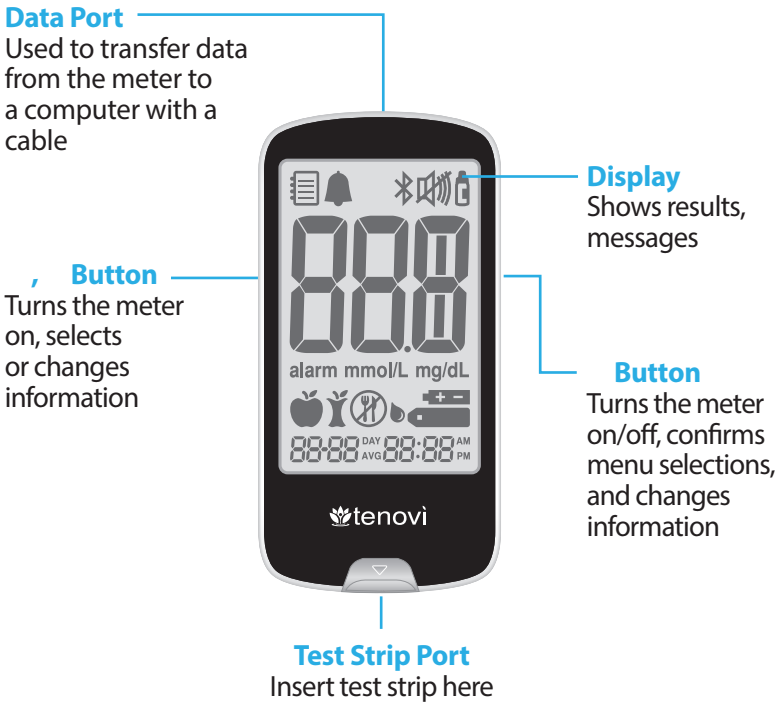
Warning!

- The Tenovi Blood Glucose 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 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 34–86 ˚F (1–30 ˚C) and 20–80 % Relative Humidity.
- 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.
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- Do not apply samples other than capillary whole blood or control solution to the test strip.
- Handle test strips 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 Tenovi test strip package insert.

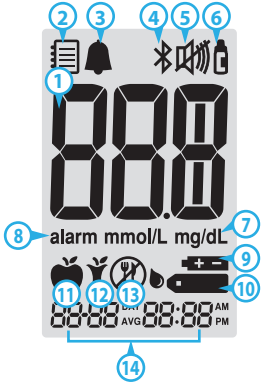
Caution:
- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Tenovi Blood Glucose Meter



Note:
- The cable for data management software can be ordered separately. Please contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST***
- The unit of measurement is fixed and it cannot be changed by the user.

Tenovi Blood Glucose Meter Display



① **Test results:** test results displaying panel
② **Memory recall mode:** appears when test results stored in the memory are displayed
③ **PP2 alarm:** appears when the post-meal alarm has been set
④ **Bluetooth symbol**
⑤ **Mute symbol:** appears only when the sound is set to OFF
⑥ **Control Solution flag:** appears when the control solution test results are saved or displayed
⑦ **mg/dL:** unit for measuring blood glucose
⑧ **alarm:** appears when the time alarm has been set
⑨ **Battery symbol:** indicates meter battery is running low and needs to be replaced
⑩ **Blood insertion symbol:** indicates meter is ready for the application of a drop of blood or control solution
⑪ **Pre-meal test flag:** used for tests done before eating
⑫ **Post-meal test flag:** used for tests done after eating
⑬ **Fasting test flag:** used for tests done after fasting for at least 8 hours
⑭ **Month/Day/Hour/Minute**

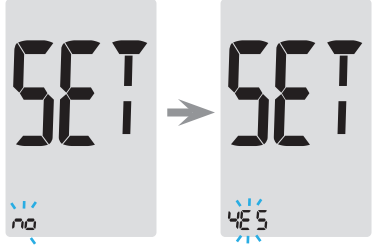
Note: It is recommended to ensure that the display screen matches the illustration above every time the meter is powered on. Do not use the meter if the display screen does not match the illustration, as the meter may show incorrect results.

Setting Up Your System

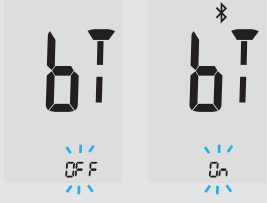
You should check and update the meter-settings such as time and date before using your meter or after changing the meter batteries.
Press and hold the ● button for 3 seconds to enter SET mode.
After all settings are finished, press and hold the ● button for 3 seconds to turn off the meter.
Press the ▲ or ▼ button to reach the accurate value. Press and hold the ▲ or ▼ button to scroll faster.

Step 1 Entering SET Mode

Press and hold the ● button for 3 seconds to enter the SET mode. 'SET' will be displayed on the screen. Press the ▲ or ▼ button to select 'YES' and then press the ● button to go to the next step.



Note: The ᛒ symbol will appear on the screen when the Bluetooth® feature is on. When the ᛒ symbol is not present on the screen, the Bluetooth® feature is off. When you need to turn off/on the Bluetooth® feature, press the button when OFF/On blinks on the screen.



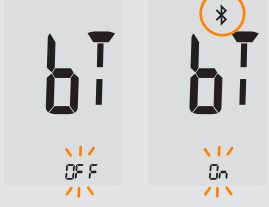
Setting Up Bluetooth

Step 2 Bluetooth Pairing

① When you do not want to connect your meter to your smartphone, press the ● button when the screen shows on the right. The meter will go to Step 4 Year Setting Mode.

② Press the ▲ or ▼ button. The meter screen shows 'OFF', 'On', and 'PAIr' in turn. To pair your meter with your smartphone, press the ● button when the screen shows 'PAIr'.

Note: The ᛒ symbol will appear on the screen when the Bluetooth® feature is on. When the ᛒ symbol is not present on the screen, the Bluetooth® feature is off. When you need to turn off/on the Bluetooth® feature, press the ● button when OFF/On blinks on the screen.

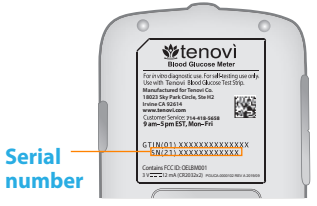


Step 3 Entering the PIN number

① The ᛒ symbol and 'PIn' will appear if you press the ● button when the meter screen shows 'PAIr'.

② Launch SmartLog mobile app to start pairing the meter with your smartphone. Find the 'Accessories' menu and select the appropriate meter model on SmartLog mobile app.

③ Look for 'CareSensNPlus' and the last 4 characters of the meter serial number on the SmartLog mobile app screen to correctly identify your meter.
Touch your meter's ID (CareSensNPlus XXXX) on the SmartLog mobile app screen.



④ The meter will display six digit PIN number.

⑤ Enter the PIN number into the SmartLog mobile app and touch 'OK'. Make sure the PIN you enter on your smartphone matches the PIN on your meter screen.

⑥ When your meter and smartphone are paired and connected, the meter will display 'SUCCESS' and the saved test results will be transferred to your smartphone.

⑦ When the data transfer is finished, the meter will display 'End' on the screen. Press the button to go to Step 10 Sound Setting mode. See page 25. If the meter displays 'FAIL' and then 'OFF', repeat steps 2 to 5.

Note:
Some smartphones, especially those that are not tested or approved by i-SENS, may be incompatible with your meter. Visit *www.i-sens.com/smartlog* for more information about supported smartphones. You can also scan the QR code on the back cover of this user manual.

Adjusting the Date and Time

Step 4 Setting the Year

Press the ▲ or ▼ button to adjust until the correct year appears. After setting the year, press the ● button to confirm your selection and to go to the next step.

Step 5 Setting the Month

A number indicating the month will blink on the screen. Press the ▲ or ▼ button until the correct month appears. Press the ● button to confirm your selection and to go to the next step.

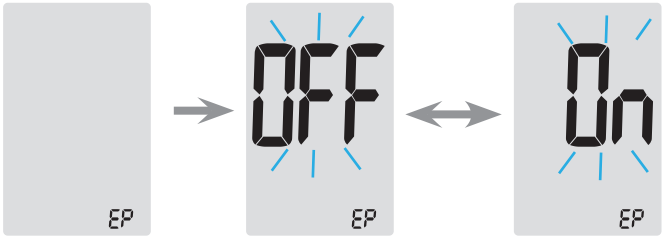
Step 6 Setting the Date

Press the ▲ or ▼ button until the screen displays the correct date. Press the ● button to confirm the date and to go to the next step.

Turning on the Strip Expiration Date Indicator

Step 11

This mode allows you to turn the strip expiration date indicator 'On' or 'OFF'. See page 28 to set the strip expiration date. When 'EP' appears on the screen, press the ▲ or ▼ button. The screen will display 'On' or 'OFF'. Press the ● button to confirm the setting. If you do not want to set the indicator, press the ● button while the screen displays 'OFF'.

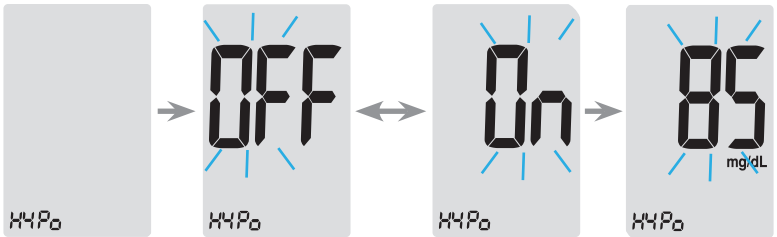


Note: If the pre-set expiration date expires, the meter will display 'EP' when the test strip is inserted. The display will alternate between 'EP', and the date and time when the test result is displayed right after the test. If the expiration date is set to October of 2022, the meter will display 'EP' at the start of October, 2022.

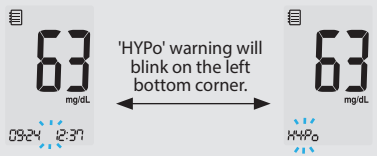
Turning on the Hypoglycemia (HYPo) Indicator

Step 12

This setting allows you to turn the hypoglycemia indicator (possible low blood sugar) 'On' or 'OFF' and to select the desired level for the indicator. You will be alerted any time your test result is lower than the selected level. On pressing the ▲ or ▼ button, the screen will display 'On' or 'OFF'. Press the ● button when 'On' appears to enter the setting. Press the ▲ or ▼ button until the desired hypoglycemia level between 20 and 90 mg/dL appears. Then, press the ● button to confirm the level and to return to step 2.



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 Strip Expiration Date Indicator

Step 1 Entering the Expiration Date Setting

Press and hold the ▲ and ▼ buttons 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 test strip vial.

Step 2 Setting the Year

A number indicating the year will blink in the left corner of the screen. Press the ▲ or ▼ button until the correct year appears.
Press the ● button 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 the ▲ or ▼ button until the correct month appears. After setting, press and hold the ● button for 3 seconds to turn off the meter.

Checking the System

You may check your meter and test strips using the Tenovi Control Solution (Control A and B).
The Tenovi 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 Tenovi Control Solution ranges printed on their labels. Compare the result displayed on the meter to the Tenovi 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 30–32.

Notes:

- Use only the Tenovi Control Solution (available for purchase separately).
- Check the expiration date printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (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 68–77 ˚F (20–25 ˚C).
- 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 46–86 ˚F (8–30 ˚C).

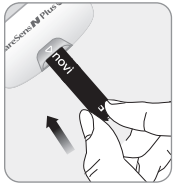
You may do a control solution test:

- 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

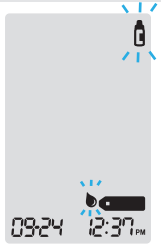
Step 1

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.

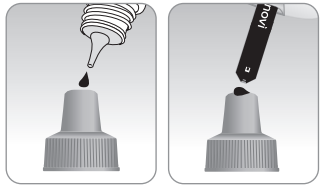


Step 2

You can flag the control solution test result by pressing and holding the ▼ button for 3 seconds. To undo the control solution flag, press and hold the ▼ button for 3 seconds again.



Step 3

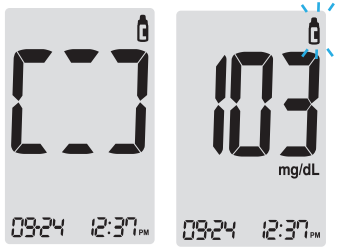


Shake the bottle before each test. Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth. Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown. After the symbol appears on the screen, 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 4

The display segments will rotate clockwise and a test result will appear after the meter counts down from 5 to 1.
When flagged, the result is stored in the meter's memory but it is not included in the averages.



Step 5

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

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

Note: The Tenovi Control Solution can be ordered separately. Contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST*** .
At all other times, contact your healthcare professional.

Comparing the Control Solution Test Results

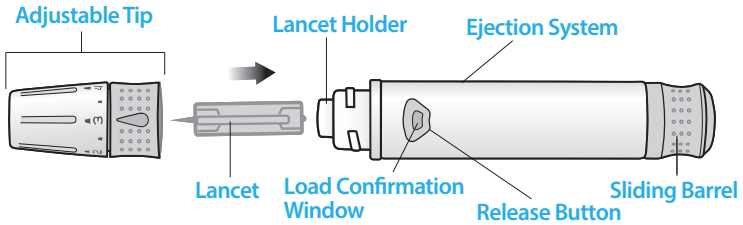
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of the range. Out of range results may occur in following situations:

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 notes on page 29.
• 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 Tenovi Test Strip and Tenovi meter may not be working properly. Do not use your system and contact Customer Service: **1-714-418-5658 (9 am–5 pm PST, Monday–Friday)** .

Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device included in the Tenovi Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device is for use by a single user only and should not be shared with anyone including other family members.
- 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:

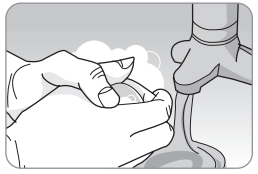
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

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.

Preparing the Lancing Device

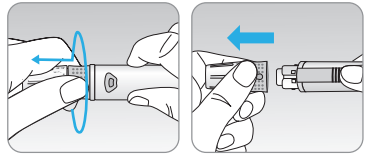
Step 1

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



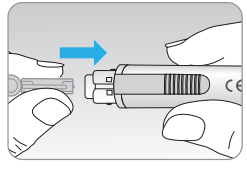
Step 2

Unscrew and remove the adjustable tip.



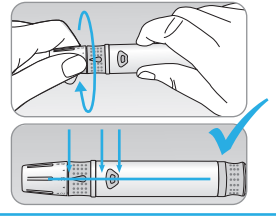
Step 3

Insert a new disposable lancet firmly into the lancet holder. Twist off the protective cover of the lancet and set it aside, then replace the adjustable tip. Keep the protective cover to replace on top of the used lancet after testing.



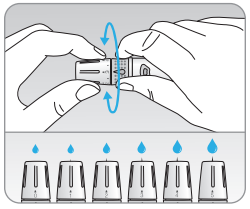
Step 4

Turn the adjustable tip until it is aligned with the load confirmation window and release button as shown in the diagram.



Step 5

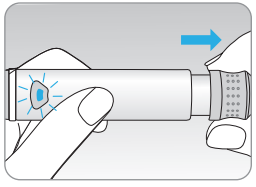
The lancing device has six puncture depth settings, numbered 0 through 5 (0 for a shallow puncture, 5 for a deeper puncture).
Choose a depth by rotating the top portion of the adjustable tip until the desired number aligns with the arrow.



Note:
0 = least penetration of lancet into the skin.
5 = most penetration of lancet into the skin.

Step 6

To cock the lancing device, hold the body of lancing device in one hand and pull the sliding barrel with the other hand. The device is loaded when you feel a click and the load confirmation window turns red.

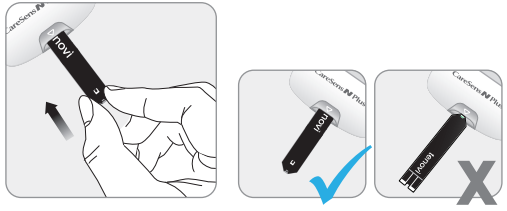


Note: The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration to get an adequate sample size.

Preparing the Meter and Test Strip

Step 7

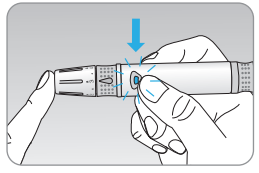
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The symbol will appear on the screen.



Applying Blood Sample

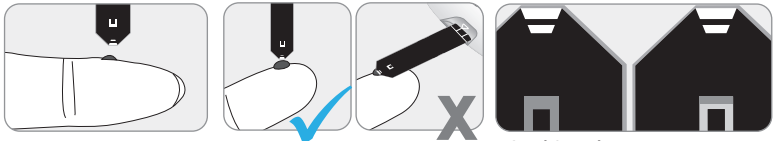
Step 8

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 lancing 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 µL: ●).



Step 9

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 10

At this time, the display segments will rotate clockwise while the blood is going in.
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.
If the Bluetooth feature is activated, the meter will send the test result to the connected smartphone.

Test result

Note: To transmit glucose data using the Bluetooth feature,

- The Bluetooth feature on the meter must be turned on,
- The meter and a smartphone must be paired,
- The SmartLog mobile app must be launched.

The meter will transmit data in the following cases,

- When the test strip is ejected after measuring,
- When the meter is turned on (only when untransmitted data exists).

Step 11

You can attach a flag to a result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press the ▲ or ▼ button to select a pre-meal flag ( ), a post-meal flag ( ), a fasting flag ( ), or a control solution 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

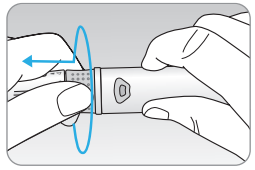
Fasting flag

Control solution flag

Discarding Used Lancets

Step 1

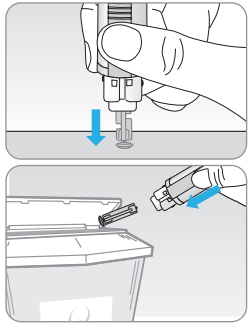
Unscrew the lancing device tip.



Step 2

Place the protective cover on the lancet.

Push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.



Caution:

- Check for damages before using the lancet. If they have been damaged, please discard it and use other lancet.
- The lancet is very sharp. Please keep away from children.
- Keep the lancets in a cool and dry place.

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

HI and Lo Messages

HI Message

The meter displays results between 20–600 mg/dL. 'HI' appears when the blood glucose level is greater than 600 mg/dL.

If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

Lo Message

'Lo' appears when a test result is less than 20 mg/dL.

If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.

Note: If you continue to get HI or Lo results and think the meter may not be functioning properly, contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST***
At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

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

Reference
American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27)

Transferring Test Results

Test results stored in the CareSens N Plus BT 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.

Meter Memory

The Tenovi 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 most recent test result will be stored. The meter calculates and displays the averages of 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 the Meter's Memory

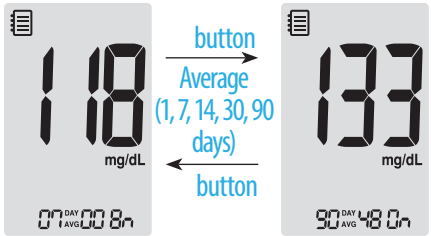
Step 1

Press the ● , ▲ or ▼ button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average and the number of the test results saved within the current day.

The number of tests within the current day

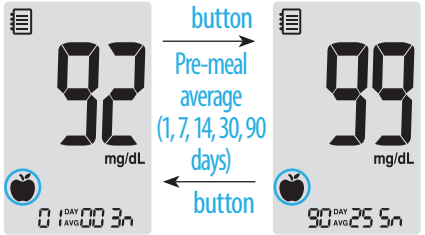
Step 2 Viewing Averages

Press the ▲ button to view 7, 14, 30 and 90-day averages and the number of tests performed for the last test period.



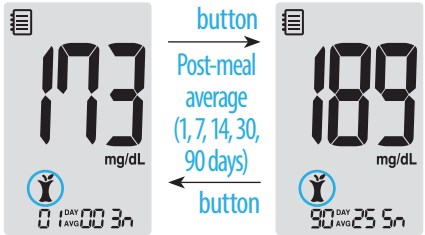
Step 3 Viewing Pre-meal Averages

Press the ▲ button to scroll through and view 1, 7, 14, 30 and 90-day averages and the number of pre-meals test performed with the ( ) symbol for the last test period.



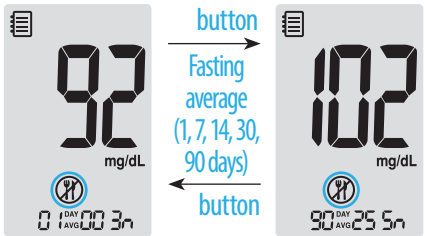
Step 4 Viewing Post-meal Averages

Press the ▲ button to view 1, 7, 14, 30 and 90-day averages and the number of post-meals tests performed with the ( ) symbol for the last test period.



Step 5 Viewing Fasting Averages

Press the ▲ button to view 1, 7, 14, 30 and 90-day averages and the number of fasting tests performed with the ( ) symbol for the last test period.



Step 6

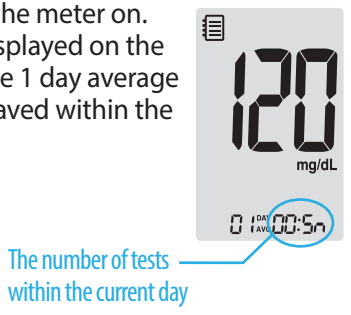
Use the ▼ button to scroll back through the averages seen previously.
Press and hold the ● button to turn off the meter.

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

Viewing Test Results Stored in Memory

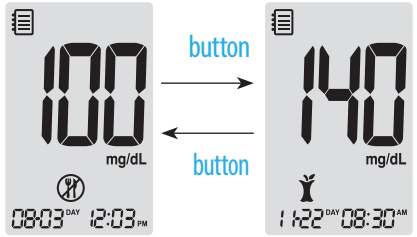
Step 1

Press the ▼, ▲ or ● button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average 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 the ▲ button to return to the result seen previously. After checking the stored test results, press and hold the ● button 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.

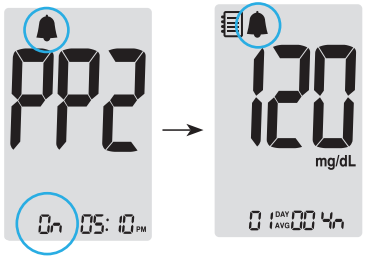
Setting the Alarm Function

Four types of alarms can be set in the Tenovi 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 any button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 alarm)

Step 1 Setting the PP2 alarm On

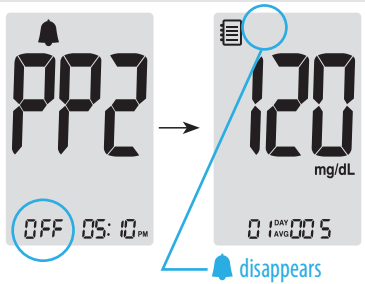
Without inserting a test strip, press and hold the ▲ button for 3 seconds to set the post-meal alarm. 'PP2', bell (🔔) symbol and 'On' will be displayed. The screen will then automatically change to the memory recall mode. At this time, bell (🔔) symbol, indicating that the PP2 alarm has been set, will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



Note: The PP2 alarm 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 alarm time.

Step 2 Setting the PP2 alarm OFF

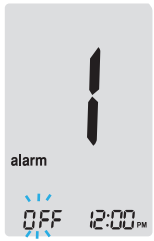
To turn off the PP2 alarm, press and hold the ▲ button for 3 seconds. 'PP2', bell (🔔) symbol and 'OFF' will appear on the screen. Then the screen will change automatically to the memory recall mode without bell (🔔) symbol displayed.



Setting the Time Alarms (alarm 1–3)

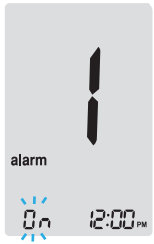
Step 1

Without inserting a test strip, press and hold the ▲and ● buttons simultaneously for 3 seconds to enter the time alarm setting. 'alarm 1' will be displayed while 'OFF' blinks on the screen.



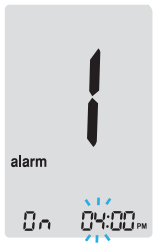
Step 2

On pressing the ▲ button, 'alarm 1' is set and 'On' is displayed on the screen. Press the ▲ button again to cancel 'alarm 1'. 'OFF' will blink on the screen.



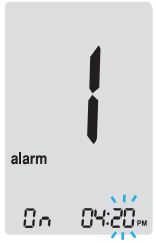
Step 3

Press the ▼ button to adjust the time of 'alarm 1'.
A number representing the hour will blink on the screen. Press the ▲ button to set the hour.



Step 4

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



Step 5

Press the ● button to finish and to go to 'alarm 2' mode.
Repeat steps 2 to 5 to set the remaining time alarms (alarm 2–3).

Step 6

Press and hold the ● 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.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

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 and lancing device before performing the disinfection procedure. The disinfection procedure is needed to prevent transmission of blood-borne pathogens.

- For the meter and lancing device, this pre-cleaning and disinfection procedure should be performed **once a week**.

Note: The life span of a Tenovi meter is 5 years. We recommend disinfecting both the meter and lancing device at least once a week. We have validated a total of 260 cleaning and disinfecting cycles (260 pre-cleaning and 260 disinfection cycles) to represent weekly cleaning and disinfecting over the life of your meter and lancing device.
1 pre-cleaning and 1 disinfection cycle per week * 52 weeks per year * 5 years = 260 pre-cleaning and 260 disinfection cycles

- We have validated **Clorox Healthcare Bleach Germicidal Wipes,** with 0.55 % sodium hypochlorite as the active ingredient, for disinfecting the Tenovi meter and lancing device. It has been shown to be safe for use with the meter and lancing device. This disinfectant is available commercially in towelette form.
  In addition to the Tenovi Blood Glucose Monitoring System instructions, 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** [Phone] 1 800 537 1415 [Website] www.cloroxprofessional.com	
EPA registration number	67619-12	
Active ingredients	Sodium Hypochlorite: 0.55 %	

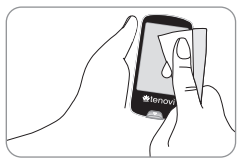
Note: This disinfectant product can be purchased through online retailers (e.g. Amazon or Walmart) or by calling the Clorox® company. To find out where to purchase this disinfectant product, please contact the Clorox® company or visit their website as listed above.

Note: Pre-cleaning procedures should always be performed before the disinfecting procedures.

Pre-cleaning and Disinfection Procedures:

① Open the cap of the **Clorox Healthcare Bleach Germicidal Wipes** container, pull out one towelette and close the cap.

② Wipe the entire surface of the meter three times horizontally and three times vertically using one towelette to remove blood and other body fluids.

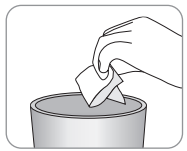


Front

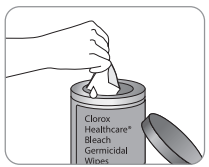

Back

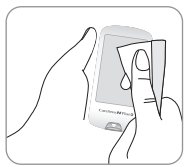

Both sides

③ Dispose of the used towelette in a trash bin.



④ To remove blood borne pathogens, pull out one new towelette and wipe the entire surface of the meter three times horizontally and three times vertically.

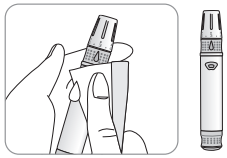




⑤ Dispose of the used towelette.

⑥ Allow the exterior to remain wet for 1 minute.

⑦ Repeat the same procedure for the lancing device (step ① to step ⑥).



*** After the pre-cleaning and disinfection procedures, perform a control solution test to ensure the meter is working properly. Verify that the test results are within the range printed on the test strip vial. See pages 30–32 for control solution testing.**

Note: If any of the following deterioration signs appear after pre-cleaning or disinfecting, please stop using the system and contact Customer Service: **714-418-5658 (9 am–5 pm PST, Monday–Friday)** . *At all other times, contact your healthcare professional.*

- When the inscriptions on the exterior of the meter (or lancing device) have been removed
- When the color of the meter (or lancing device) has changed or faded
- When cracks or roughness develop on the meter (or lancing device)
- 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

Caution:

- Do not use other cleaners or disinfectants. Other chemicals have not been validated and may damage the meter.
- 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.

Caution:

Storage and Handling 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 subject it to strong shock.
- Keep out of reach of children.
- Do not try to fix or alter the meter in any way.
- Keep the meter in a cool and dry place.
- The Tenovi meter should be used only with Tenovi test strips.
- Store all meter components in the carrying case to prevent loss.
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- Do not apply samples other than capillary whole blood or control solution to the test strip.
- Do not subject the meter and test strips to excessive heat.
- Use of the meter adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the meter and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by Tenovi could result in increased electromagnetic emissions or decreased electromagnetic immunity of the meter and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the meter, including cables specified by Tenovi. Otherwise, degradation of the performance of the meter could result.

Caution:
Do not allow any foreign substances or liquid 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 or control solution samples directly to the test strip port.
- Do not apply the blood or control solution samples to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood or control solution samples 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.
- Make sure to follow the Pre-cleaning and Disinfection Procedures found in the Caring for Your System section of this user manual.

Note: You can get additional information or technical assistance by calling Customer Service Center: ***714-418-5685 Mon–Fri, 9 am–5 pm PST***. *At all other times, contact your healthcare profession.*

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 (42.8–111.2 ˚F/ 6–44 ˚C) and repeat the test after the meter and test strips have reached a temperature within the operating range.
	The blood sample has insufficient volume. > Repeat the test with a new test strip.

	This error message may appear when the wrong blood glucose test strip is used. For use with Tenovi strips only. > Repeat the test with a Tenovi test strip.
	There is a problem with the meter. > Do not use the meter. Contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST***. *At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*
	There is a problem with Bluetooth communication. > Contact Customer Service: **714-418-5685 *Mon–Fri, 9 am–5 pm PST*** . *At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*
	An electronic error occurred during the test. > Repeat the test with a new test strip. If the error message persists, contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST*** *At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*

Note: If the error messages persist, please contact Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST***
At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

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 to 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 Customer Service: ***714-418-5685 Mon–Fri, 9 am–5 pm PST***
At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

Performance Characteristics

The performance of Tenovi Blood Glucose Monitoring System has been evaluated in laboratory and clinical tests.

Accuracy: The accuracy of the Tenovi BGM 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	1.0223
Y-intercept	-1.3686
Correlation coefficient (r)	0.9934
Number of Subjects	371
Range tested	48–553 mg/dL

Accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
61.0 % (25/41)	97.6 % (40/41)	100 % (41/41)

Accuracy results for glucose concentration ≥ 100 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
70.0 % (231/330)	96.1 % (317/330)	100 % (330/330)	100 % (330/330)

User performance results for glucose concentrations between 48 mg/dL and 553 mg/dL.

Within ± 15 mg/dL and Within ± 20 %
371/371 (100 %)

Precision: The precision studies were performed in a laboratory using the Tenovi BGM Systems.

Within Run Precision			
*Bloodav	43 mg/dL	SD = 1.9 mg/dL	CV = 4.3 %
*Bloodav	71 mg/dL	SD = 2.1 mg/dL	CV = 2.9 %
*Bloodav	135 mg/dL	SD = 3.8 mg/dL	CV = 2.8 %
*Bloodav	203 mg/dL	SD = 5.2 mg/dL	CV = 2.6 %
*Bloodav	343 mg/dL	SD = 11 mg/dL	CV = 3.2 %

Between Run Precision			
*Controlav	36 mg/dL	SD = 1.4 mg/dL	CV = 3.8 %
*Controlav	114 mg/dL	SD = 3.4 mg/dL	CV = 3.0 %
*Controlav	341 mg/dL	SD = 8.2 mg/dL	CV = 2.4 %

EMC Table

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2:2014 (Fourth Edition).

Phenomenon	Basic EMC standard or test method	Port tested	Test level/ requirement
Radiated disturbance	CISPR 11: 2015 +A1: 2016	Enclosure	Group 1, Class B
Electrostatic Discharges (ESD)	IEC 61000-4-2:2008	Enclosure	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air
Radiated RF Electromagnetic Fields	IEC 61000-4-3:2006 + A1:2007+A2:2010	Enclosure	3 V/m 80 MHz to 2.7 GHz 80%, 1 Hz AM RF Wireless Comm. (Refer to test report clause 1.15)
Electric Fast Transients and bursts	IEC 61000-4-4:2012	AC Mains	±2 kV AC, 100 kHz PRR
Surges	IEC 61000-4-5:2014	AC Mains	±0.5 kV, ±1 kV L1 to L2 (DM)
Conducted Disturbances, induced by RF fields	IEC 61000-4-6:2013	AC Mains	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz
Power-frequency Magnetic Field	IEC 61000-4-8:2009	Enclosure	30 A/m

Warranty Information

Manufacturer's Warranty

Tenovi warrants that the Tenovi Glucose Meter shall be free of defects in material and workmanship in normal use for a period of 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.

Tenovi 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, Tenovi 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 Tenovi Authorized Warranty Station.

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