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*Seeing Beyond Imagination*

# TensorTip™ Combo-Glucometer™ User Guide

**CNOGA Medical Ltd.**
**TensorTip™**
**Combo-Glucometer™**
**User's Guide**
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# 1 Introduction

Congratulations on purchasing our TensorTip medical device. We at Cnoga Medical put all our efforts into quality and accuracy when designing and manufacturing our devices. Please read this manual thoroughly in order to achieve maximum usage of the device.

## What is the TensorTip

TensorTip is a family of non-invasive devices that enable quick and painless measurement of physiological parameters. The Combo-Glucometer is a member of the TensorTip family to measure blood glucose level by simply inserting your finger into one compact and simple device.

## Intended use

The Combo-Glucometer has an add-on device that is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood (*in vitro*) for the purpose of personal calibration of the non-invasive TensorTip device.

After the calibration Process is completed, the Combo-Glucometer will inform that you can start measuring yourself using the non-invasive TensorTip measurement device.

## Safety Notes for the TensorTip Device

- Read this user guide before using your TensorTip
- Do not use the TensorTip on an injured finger
- Do not use the TensorTip on a dirty or wet finger
- The TensorTip should NOT BE used by children under the age of 18.
- Do not use the device as sole diagnostic indicator.
- Do not use the non-invasive component as sole indicator for treatment.
- Do not look directly into the TensorTip Measurement Chamber
- The device contains no user-serviceable parts. In case of a technical problem the device should be repaired by an authorized technician only.

- Do not drop the device. If the device is dropped accidentally do not use it before consulting with an authorized technician.
- The TensorTip should not be stored with common household waste products.
- The device is not intended for use in the presence of water or flammable substances.
- The TensorTip is classified as Internally Powered equipment when battery operated and Class II when mains powered. It is also classified as for continuous operation, with a Type BF Applied Part.

## Safety Notes for the invasive add-on component

The following basic safety precautions should always be taken:

- Close supervision is necessary when the device is used near children, handicapped persons or invalids.
- Use the device only for the intended use described in this manual.
- Do not use test strips and control solutions that are not supplied by Cnoga Medical Ltd.
- Do not use the device if it is not working properly, or if it has suffered any physical or mechanical damage.

## Warnings, Cautions and Notes

Cautions and Notes are used throughout this manual:

**Caution**

A caution indicates instructions, or cautionary notes which, if not followed, may result in a damage to the equipment or to the quality of measurements

*Note*

*Notes contain helpful information and tips*

**Warning:** Keep the test strips and vial away from children; the vial cap and the test strips can be a potential choking hazard. Never chew or swallow a test strip. If this occurs, please seek medical assistance immediately.

## Intended use for invasive module

The device is intended for the use outside the body (in vitro diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

## Test Principle

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagent (special chemicals) on the test strip. The electrical current changes with the amount of glucose in the blood sample. The meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either mg/dL or mmol/L.

## Inside the Box

Tensor Tip is supplied with the following components:

- Combo-Glucometer
- 220v/50Hz or 115v/60Hz Battery Charger
- Strips (400)
- Lancing Device
- Lancets (200)
- Stand/Finger Chamber device
- User Manual and Quick manual
- Protective pouch
- Invasive add-on device
- Finger wipes
- Pouch

## Indications for Use

The Combo-Glucometer is combined by two components. A component for the quantitative measurement of fresh whole blood using test strips and a component to measure noninvasive Glucose level from the fingertip pursuant personal calibration. Any person may perform test strip readings of fresh whole blood but only the calibrated person may use the non-invasive reading. Only the chosen finger shall be used for the calibration and the non-invasive reading thereof. Do not use the selected finger for the non-invasive readings for the extracting of whole blood samples.

It is intended to be used by any person above 18 years old, who complies with the device instructions and finger fits the chamber.

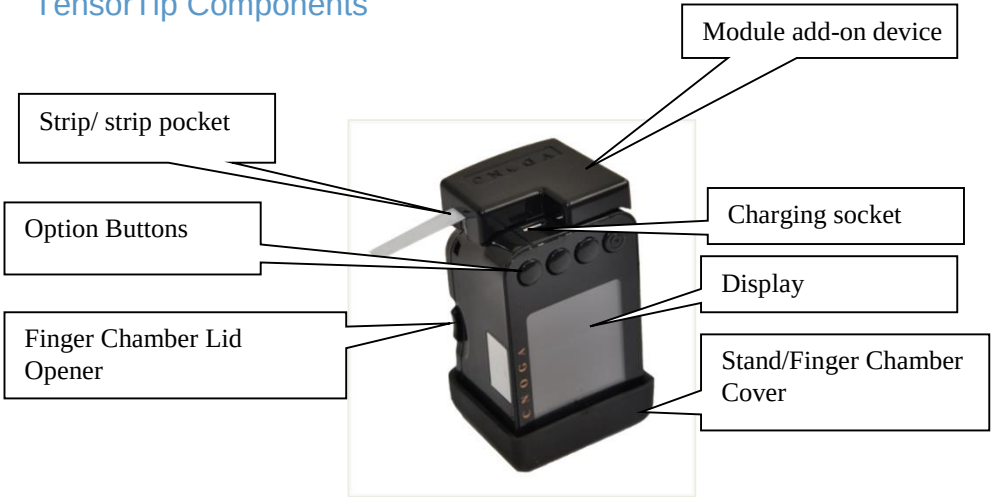
**Caution**

***To avoid damaging the device, do not ever attempt to push your finger into or pull your finger out of the Finger Chamber with the lid closed. Always open the lid to insert or extract your finger***

Correct

Incorrect

## TensorTip Components



## Device Care

The TensorTip contains sensitive electrical and electronic components and therefore:

- Take care not to drop or damage the device.
- When not in use store your TensorTip inside its pouch in a dry protected environment.
- Do not leave in direct sunlight or inside a car.
- Do not expose the TensorTip to water or heat.
- Do not leave the plastic cover inside the chamber after self-calibration is performed.

## Health-Related Information for the invasive add-on component

- Apply only capillary whole blood samples to test your blood glucose. Applying other substances or plasma, serum will cause incorrect results.
- Severe dehydration and excessive water loss may cause false or low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this user's manual, consult your healthcare professional.
- Test results below 50 mg/dL (2.8 mmol/L)[*1] may mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)[*2] may

mean high blood glucose (hyperglycemia). If your results are below 50 mg/dL (2.8 mmol/L) or above 240 mg/dL(13.3 mmol/L), repeat the test, and if the results are still below 50 mg/dL (2.8 mmol/L) or above 240 mg/dL(13.3 mmol/L), follow the treatment advice of your healthcare professional.

- Inaccurate results may occur in severely hypertensive 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.
- Measuring Range 20 – 600 mg/dL (1.1 – 33.3 mmol/L)
- Acceptable Hematocrit Range 20~60%.

- Abnormal red blood cell counts (Hematocrit levels below 20% or above 60%) may cause incorrect results. Please consult your healthcare professional if you do not know your Hematocrit level.
- Interference: Reduced substances occurring in the blood naturally (uric acid) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect the test results. However, elevated concentrations of these substances may affect test results. The compounds listed in the tables were found to have no affect at the concentration indicated.
- A sample with large amount of reduced substances such as ascorbic acid and uric acid may cause results slightly higher than the actual glucose level.

| Compounds | Uric Acid | Gentisic Acid | Acetaminophen | Hydroxyurea | Ascorbic Acid |
|---|---|---|---|---|---|
| Lowest concentrations tested at which no interference occured | ≦ 8.0 mg/dL (0.47 mmol/L) | ≦ 5.0 mg/dL (0.33 mmol/L) | ≦ 8.0 mg/dL (0.53 mmol/L) | ≦ 3 mg/dL (0.39 mmol/L) | ≦ 5.0 mg/dL (0.29 mmol/L) |

| Compounds | Dopamine | L-dopa | Methyldopa | Tolbutamide | Triglycerides |
|---|---|---|---|---|---|
| Lowest concentrations tested at which no interference occured | ≦ 2.0 mg/dL (0.11 mmol/L) | ≦ 10 mg/dL (0.51 mmol/L) | ≦ 3.0 mg/dL (0.12 mmol/L) | ≦ 400 mg/dL (15 mmol/L) | ≦ 2000 mg/dL (43 mmol/L) |

8. Please refer to your test strip package insert for additional important information.

REFERENCE:

*1: Jabbour, Serge, Elizabeth A. Stephens, Irl Bennett Hirsch. Type 1 Diabetes in Adults. USA: CRC Press, 2007

*2: Unger, Jeff. Diabetes Management in Primary Care. USA: Lippincott Williams & Wilkins, 2006

## ALTERNATIVE SITE TESTING (AST)

There are important limitations for doing AST. Please consult your healthcare Professional before you perform an AST.

### What is AST?

Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The invasive add-on device allows you to test your palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing.

### What is the advantage?

Fingertips feel pain more readily as they have a large concentration of nerve endings (receptors). At other body parts, nerve endings are not so concentrated and you will not feel as much pain as you will experience on the fingertip.

## When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood on other parts. Therefore, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.

# 2 Using the Combo-Glucometer

## Charging and Recharging TensorTip

Before using TensorTip Combo-Glucometer for the first time, you need to charge the device. To charge the TensorTip, plug the USB cable connected to the charger into your TensorTip (Figure 1) and the charger to the mains. Leave the TensorTip plugged in until the battery icon indicates full and the "Battery charging complete" message appears on the screen.

When the battery symbol indicates  , the rechargeable battery is exhausted and you must recharge.

Figure 1: USB Port

***Note***

If the display is blank and the button does not turn the device on, the battery is completely discharged and recharging is necessary. Once the battery is charged, press the button to turn the device back on.

**Caution**

Even if the device is not in use the battery must be charged every three months. Failing to do this may result in permanent damage to the battery.

***Note***

The battery cannot be removed by the user.

## Turning the Device On and Off

TensorTip turns on automatically when you initiate a measurement, and turns off automatically 30 seconds after the last time any button was pressed. You can also manually turn the device on by pressing the On/Off button ( ).

***Note***

TensorTip will not automatically turn off during measurement, even if no button was pressed for 30 seconds.

## Icons

The following icons are used in the interface:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
|  | Back |  | History |  | Calibration is in progress |  | Add-On Device connected |
|  | Strip Inserted |  | Used strip inserted |  | USB Connection |  | CBG Units |
|  | First invasive reference |  | Second invasive reference |  | Non-invasive reference |  | Stop |
|  | Battery Status |  | Next |  | Retry |  | Scroll Up |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
|  | Accept |  | Reject |  | Save Results |  | Scroll Down |
|  | Increase |  | Decrease |  | Progress indicator |  | Inadequate Signal |
|  | Switch display mode |  | Switch graphs display mode |  | Brightness |  | sample is valid |
|  | Sample is not valid |  | not valid by system |  | Low Battery Indicator | | |

## First-time Operation

The first time TensorTip is activated, the date and time must be set and the devices self-test must be run. If the self-test is not completed successfully or if the date and time are not set, TensorTip will not allow normal operation.

For instructions regarding running the devices self-test, see page 34

If the add-on device is not connected and the Combo-Glucometer is calibrated, operation will be as the standard TensorTip Combo-Glucometer.

If the add-on device is not connected and the Combo-Glucometer is not calibrated a message will be displayed whereas calibration is needed.

## Language selection

The TensorTip is a multilingual device whereas the user can select the desired language of operation. In order to change operating language, choose Language from the Main Menu, Options, User Settings menu. Press the and buttons to select desired language.

## Product Self-Test

TensorTip includes a self-test procedure to ensure that measurements provide accurate results. The self-test requires minimal user intervention, as described below. It is initiated in the following conditions:

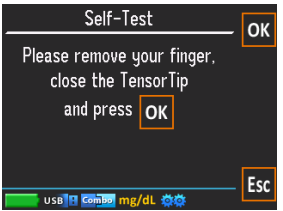
- During the first-time operation of TensorTip.
- Periodically requested by the device
- By user request, from the Options menu.

Access Self-Test via **Main Menu**, **Options**, **Factory Settings, Self-Test**

***Note***

The device will not allow measurement and any other operation until the self-test is successfully completed. Make sure you follow the TensorTip maintenance instructions to avoid self-test failures**.**

1. Extract your finger from the chamber.

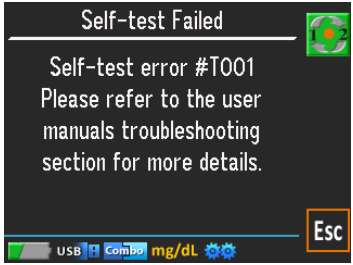


2. Insert the arc black plastic into the chamber when the small pin of the arc goes into the small hole in the chamber center.

3. Close the lid.
4. Close the chamber entrance by the "finger chamber cover".

5. Press the button near the OK icon.
6. The screen will turn red, green and blue accompanied by tones (in some models).
7. The progress indicator appears

8. A successful self-test or failure message appears. If the self-test failed see Troubleshooting, page 92




## Tips for performing a successful measurement

Keep in mind the following points while performing the measurement. It is explained in further detail in the Measurement Procedure section.

- Do not perform the measurement when your finger is cold.
- Do not perform measurement after physical exercise.
- Make sure your heartbeat is close to normal before performing a measurement.
- Be in a relaxed state when performing a measurement.
- You should be in a sitting position with your elbow resting on a firm surface.
- Your wrist should be relaxed and arm extended.

- The device should hang on the finger downwards below the heart level slightly raised above the supporting surface. See Figure 2.
- Clip your fingernail.
- Make sure the fingertip is intact and wiped. If your fingertip is damaged try using the ring or pinkie finger. Make sure that the lid of the Finger Chamber is closed properly and that your finger is firmly in place.

**Figure 2: Measuring Position**

## Key Function of the Test Strip


1. **ABSORBENT CHANNEL**: apply a drop of blood here; the blood will be drawn in automatically
2. **CONFIRMATION WINDOW**: this is where you confirm if enough blood has been drawn into the test strip's absorbent channel.
3. **TEST STRIP HANDLE**: hold this part to insert the test strip into the meter slot.
4. **CONTACT BARS**: Insert this end of the test strip into the meter until it will go no further.

## Important Test Strip Information

1. Test strips are for single use only.
2. Store the vial in a cool, dry place below to 40° C/104° F and above 4° C/39° F. Do not refrigerate.
3. Store your test strip in their original vial only. Do not transfer them to a new vial or any other container.
4. With clean, dry hands, you may touch the test strip anywhere on its surface when removing it from the vial or inserting it into the meter.
5. Immediately use a test strip after removing it from the vial, replace the vial cap and close it tightly.

6. Only apply a blood sample or a control solution sample to the test strip's absorbent channel. Applying other substances to the test strip's absorbent channel will cause inaccurate results.
7. Record the discard date on the vial label when you first open it. The discard date for test strips is 90 days after first opening the vial. Discard remaining test strips after the expiry date or period.
8. Do not use test strips beyond the expiration date indicated on the strip vial label.
9. Do not place in direct heat or sunlight.
10. Do not carry loose test strips in your carrying case.
11. Do not use damaged test strips or test strips that have changed in any way.

## Control Solution Test

Control solutions contain a known amount of glucose that reacts with the test strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you are making sure that the meter and the test strips are working properly together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

### Why perform a control solution test?

1. To ensure that your meter and test strip are working properly together.
2. To allow you to practice testing without using your own blood.

## When should the control solution test be performed?

1. When you first get your TensorTip Combo-Glucometer. Before using this system to test your blood, you can practice the procedure by using control solution. When you do three tests in a row that are within the expected range, you are ready to test your blood.
2. Once a week (to make sure that you continue to get accurate results).
3. When you begin using a new vial of test strips.
4. Whenever you suspect that the meter or test strips are not working properly.
5. When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
6. When test strips are exposed to extreme environmental conditions.

7. If you drop the meter.

## Important Control Solution Information

1. Use only Cnoga control solution.
2. Check the expiration date on the control solution bottle. Do not use if expired.
3. Control solution, meter, and test strips should come to room temperature (68-77 ºF/20-25ºC) before testing.
4. Shake the control solution bottle before use; discard the first drop of control solution after squeezing, wipe off the dispenser tip to avoid contamination. These steps ensure you will get a good sample and an accurate result.

5. The discard date for control solution is 90 days after first opening. Record the discard date on the bottle, when you open a new bottle of control solution.
6. Store the control solution closed at temperatures below 30ºC (86ºF). **Do not refrigerate.**

Note:

1. There are two levels of control solution (normal and high) available to choose from. The control solution supplied with the meter kit is normal range. Please contact with your local distributor for other levels of control solution.

2. The control solution range printed on the test strip vial is for OKmeter Control Solution only. It is used to test meter and strip performance. It is not recommended range for your blood glucose level.

## Performing a Control Test:

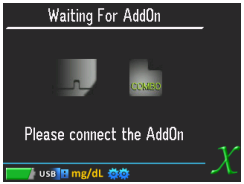
STEP 1: Turn Glucometer device on manually by holding the On/Off button ( ) for 3 seconds.

STEP 2: Activate Control Solution Test Mode

Choose Control Solution Test from the Main Menu, Options and follow displayed on the screen instructions:

STEP 3: Connect the module device (relevant only if the module is not connected)

Connect the module to the Glucometer; make sure it is well connected. The icon will appear in the status bar of device screen marking the connection. Wait till




device will complete module connection validation and will instruct you to insert a test strip.

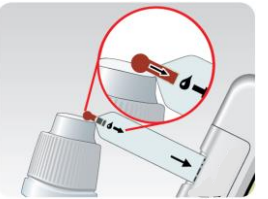
### STEP 4: Insert Test Strip

Insert a new test strip into the strip slot, in the right direction. Wait until the device completes strip validation and instructs you to apply a control solution.


### STEP 5: Apply a drop of Control Solution

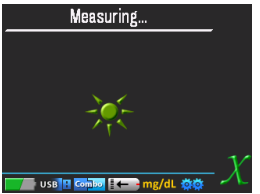
Shake the control solution bottle well. Remove the cap. Squeeze the bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton.

Squeeze the bottle again to get the second drop onto a clean non-absorbent surface or on your fingertip first.



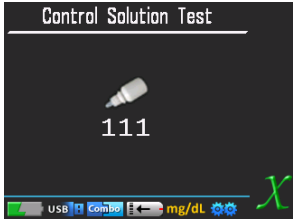
### STEP 6: Apply Control Solution

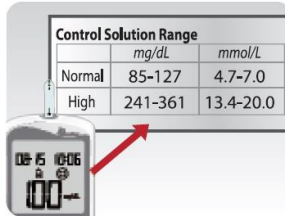
Apply the drop to the opening of the strip absorbent channel until the confirmation window is filled. The device begins to measure.



## STEP 7: Check if the test result is in range

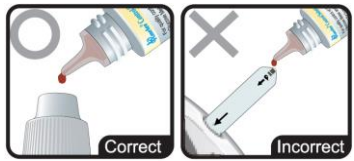
After measurement completion the test result shows up. Compare the test result with the range printed on the test strip vial. The result should fall within the printed range.



Note:

1. To avoid contaminating the control solution with the content of the test strip, DO NOT APPLY THE CONTROL SOLUTION DIRECTLY TO THE TEST STRIP!




2. If test result falls outside the range printed on the test strip vial, repeat test first. If you continue to get the result falling outside the range, your meter and test strip may not be working properly. DO NOT use the system to test your blood until you get a test result falls within the control range. If you are unable to resolve the problem, please contact your local distributor for help.

## Control solution storage:

- Storage condition: Store the control solution tightly closed at temperatures below 86° F (30° C). Do not refrigerate.

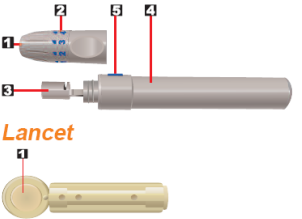
- Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.

# PREPARE FOR BLOOD SAMPLING

## Adjustable Lancing Device

Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.

1. Lancing Device Cap
2. Depth Selector
3. Lancet Holder
4. Cocking Control
5. Release Button



## Lancet

1. Protective cap

## Important Lancing Device and Lancets Information

1. Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.
4. The lancing device and lancets are in conformity with MDD 93/42/EEC. Refer to product labels for contact information of manufacturer and CE marking

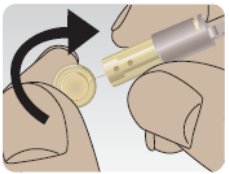
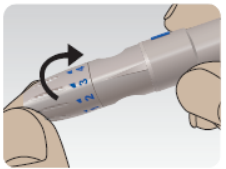
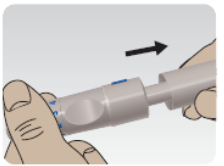
## Set Lancing Device

1. Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.

2. Twist off the protective cap until it separates from the lancet.

3. Replace the lancing device cap and set the puncture depth to the desired number. Note: The depth selector offers 5 levels: 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin.

4. Pull back the cocking control until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.

## Important Notes:

- The device only requires a very small sample of blood to perform a test. Choose a different site each time you test. Repeated puncture in the same spot may cause soreness and calluses.
- The first drop of blood usually contains tissue and serum, which may affect the test result. It should be discarded.
- The blood should completely fill the confirmation window before the meter begins the countdown. If you find that the confirmation window is not filled with blood when the meter is counting, NEVER try to add more blood to the test strip. Discard the test strip and retest with a new one.
- If you do not apply a blood sample within three (3) minutes, the glucometer will automatically turn off. You must remove the test strip and re-insert it again to turn on the meter and restart the test procedure.

## Combo-Glucometer calibration procedure

Each measurement that is performed during the calibration procedure includes 2 (two) invasive and 1 (one) none-invasive measurement. The sequence can be any of the following: Invasive – Non-Invasive – Invasive or Non-Invasive – 2 Invasive. The device will give you the instructions according to what your first measurement (invasive or non-invasive)

## Suggested calibration schedule:

Following is the suggested daily schedule for performing your calibration measurements:

- Upon wake up
- Before breakfast
- 1-2 hours after breakfast
- Before lunch
- 1-2 hours after lunch
- Before dinner
- 1-2 hours after dinner
- Before going to sleep

## Important Notes

1. The timing of the measurement after meal should be synchronized with your personal sugar levels slope. If your sugar levels tend to slope adjacent to the meal, you should perform the measurement within one hour after the meal. If your sugar levels tend to slope late after the meal, you should perform the measurement two hours after the meal or even later.

2. Make sure your selected finger site aimed for the non invasive reading is clean, intact and sufficiently warm.

3. Once calibration is completed, schedule a measurement plan similar to the calibration schedule set above. Avoid movement or different seating position.

4. Results are accumulated during the measurement process; the highest accumulated pick represents your current estimated blood glucose level.

### STEP 1: Wash Your Hands and the Puncture Site

Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.

### STEP 2: Turn Glucometer device On

Turn the device on manually by holding the On/Off button ( ) for 3 seconds.

### STEP 3: Connect the module device (relevant only if the module is not connected)

Connect the module to the Combo-Glucometer; make sure it is well connected. The icon Combo will appear in the status bar of device screen marking the connection.

### STEP 4: Insert Test Strip

Extract a new test strip from vial. Be sure to tightly replace the vial cap after removing test strips. Insert the

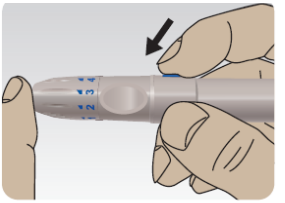
test strip immediately into strip slot as illustrated, in the right direction. Please follow displayed on the screen instructions:


Wait till device will complete strip validation and will instruct you to apply a blood sample.

## STEP 5: Select and Lance a Puncture Site


For Fingertip:

- Hold the prepared lancing device firmly against the side of your fingertip. Press the release button.



For AST:

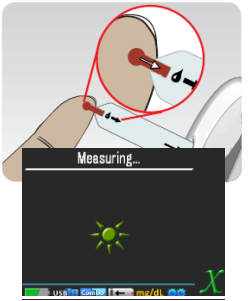
- Please refer to the "About Alternative Site Testing (AST)" Section. Please consult your healthcare professional before obtaining blood from anywhere other than your fingertip.
-

### STEP 6: Obtain a Blood Sample

Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.7uL of blood sample. Do not smear the blood sample. **To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.**

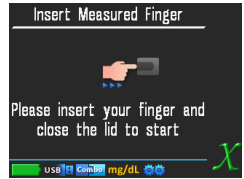
### STEP 7: Apply Blood Sample

Apply the blood sample to the opening of the absorbent channel of the test strip until the confirmation window is fully covered with blood. The device will begin the measurement.

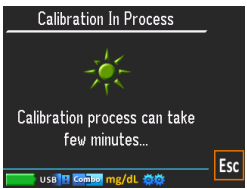


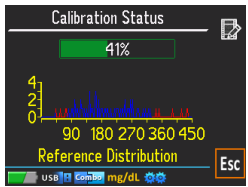
## STEP 8: Start the non-invasive measurement

After completion of blood sample measurement you will be requested to perform the non-invasive measure. Please follow the following steps in next section.

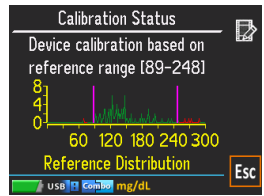



STEP 9: After you have successfully performed the 3 measurements (2 invasive and 1 non-invasive) the device will display the results of all successful measurements and sample integration process will start automatically. On completion of process you will be notified if device calibration is completed or not and a distribution of your personal values will be displayed.



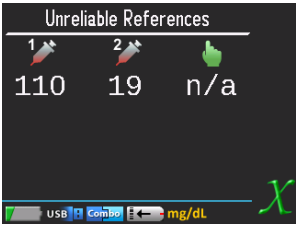




1. Number of required calibration valid tests is at least 100 if minimum glucose level is above $60\frac{mg}{dL}$ otherwise it may reach at least 150 valid tests).
2. Following calibration completion, you can widen your calibration range by adding samples outside the green range (area colored in red on your calibration status display)

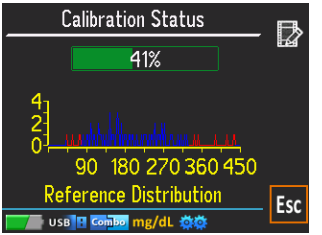
## Valid Test:

Two consequent invasive tests are within 20% gap are considered valid pair of references, otherwise it considered as invalid invasive reference.

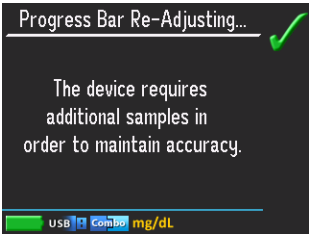


## Progress Bar:

During the calibration procedure, updated progress bar will be presented at the end of successful calibration session.




The process may also regress if some marginal values were added to the reference log. The following notification will appear. Continue the calibration process as usual.



## Performing a non-invasive Measurement:

Performing a measurement is simple; while in a sitting position, open the Finger Chamber Lid, insert your finger, close the lid, and turn the screen towards you. The measurement will start automatically.

Step 1**:** Before performing a measurement, make sure your fingernail is clipped and then clean your finger tip using the finger wipe provided with your TensorTip. Dry your finger. Performing a measurement on a dirty or greasy fingertip may affect the functioning of the device.

Step 2**:** Open the lid of the Finger Chamber by pushing the on button. **Do not attempt to push your finger into the chamber without opening the lid**.

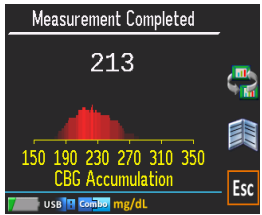
Step 3: While holding TensorTip with your right hand, insert the index, middle or ring finger (depending on which best fit) of your left hand with the bottom side of your finger in contact with the Chamber floor and touching the front of the Chamber. Use only the selected finger for the calibration procedure and for the non-invasive reading. DO NOT EXTRACT BLOOD SAMPLES FROM THE SELECTED FINGER. The fingertip should not be pushing the front of the chamber, and should completely cover the Chamber Lens (Figure 3).

Step 4: Close the lid of the Finger Chamber.

Step 5: Turn your hand so that TensorTip is facing you. The device should be held slightly above the supporting surface at a position lower than your heart. Do not move or change position during the measurement.

Step 6: TensorTip will automatically start the measurement and results will be shown within several seconds (if device calibration was completed).

Open the lid and withdraw your finger to end the measurement this part of the measurement. The device will then automatically turn off after 30 seconds if no additional buttons are pressed. To abort the measurement and return to the Main Menu, press the Esc button.



During the calibration stage you will be asked to perform another invasive reading. If so, follow the instructions displayed on the screen and repeat the steps as specified in the previous section.

***Note***

If a "Try again" massage is displayed, take your finger out of the chamber and put it in again for another measurement.

## Performing Test of Whole Blood Measurement:

Insert strip into the Add On component. Wait until drop of blood icon appears on the TensorTip screen. Apply whole blood sample. On completion, press X (last button) to abort calibration procedure. Test result will appear on the TensorTip screen.

## TensorTip Calibration procedure

- When sufficient number of tests is performed (at least 65 and may reach 100) the Combo-Glucometer will have enough information and will inform you that the calibration process is done for a specific range. From now on you may start measure yourself by non-invasively.
- At any given time you may measure yourself invasively.
- At any given time you may add a new calibration measurement (invasive and non-invasive measurement), for instruction see calibration procedure, page 58.

- After the calibration process is complete, you can choose either taking the module out or leaving in connected, in both cases you will use only the non-invasive measurement.
- Measurement procedure is identical to the calibration procedure only without the invasive measurement. See page 65 – "Performing a non-invasive measurement" for instructions.

***Note***

If a "Try again" massage is displayed, take your finger out of the chamber and get it in again for another measurement. If "Try again" massage repeats itself twice it is highly recommended to make another calibration measurement (invasive and noninvasive measurement) at that time.

**Caution**

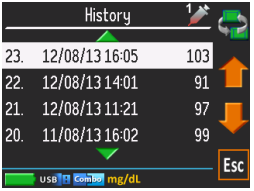
Do not try to force your finger into or out of the opening in the Finger Chamber as this will damage the seal and may affect the device function.

Make sure the device is attached to your finger properly. If the finger is too small and does not fill the Finger Chamber; the device might fall and be damaged.

Make sure the Finger Chamber Lid is closed properly. Do not force the lid on the finger if the finger is too large to fit in the Chamber.

## Viewing History

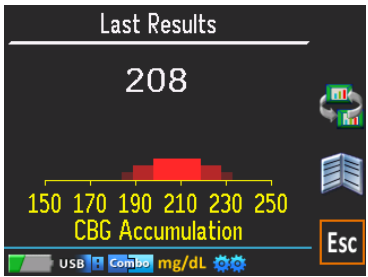
Viewing the measurement result history can be initiated either when a measurement has been stopped by pressing , or by selecting **History** in the **Main Menu**. Once in the **Result History** screen, press and to scroll up and down, and to switch between the parameters being displayed in the result list (first invasive result, second invasive result or non-invasive result).

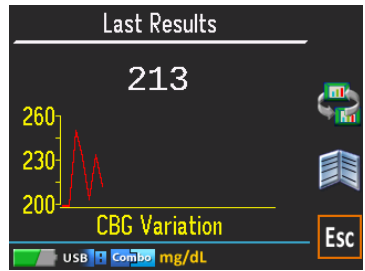




## Viewing Last Results

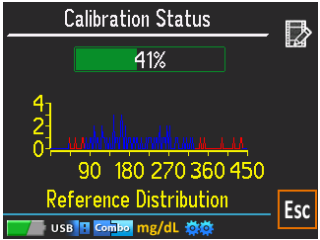
In the **Main Menu** choose **Last Results**. The previous last result will be displayed. If your results are below or above the calibrated distribution range the numbers will be displayed in yellow. Use  to switch between the displays.



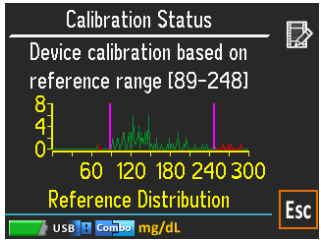



## Viewing Device calibration Status

In the **Main Menu** choose **Calibration Status**. The graph represented personal reference distribution will be displayed. If device calibration is completed the calibration range will be displayed.




**Picture A:**
Calibration is in process



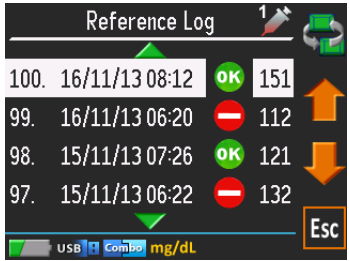

**Picture B:**
Calibration is completed within the range of the pink reference bar.

## Viewing Reference Log

**Reference Log** can be displayed from **Calibration Status screen** by pressing button.

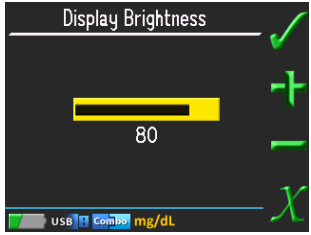
This feature allow you to overwrite validity of any one of valid samples exists in the measurement log.

Press and to scroll up and down to select the desired sample.



## = Adjusting Display Brightness

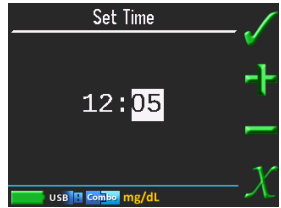
Choose **Display Brightness** from the **Main Menu, Options, User Settings**. Press the + and − buttons to adjust.



## Setting Date and Time

Access Set Date and Time from **Main Menu**, **Options**, **User Settings .**

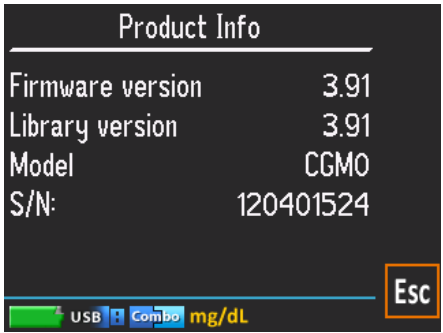

Set date: Use the + and − buttons to adjust each parameter. Use the OK button to move between parameters. When finished, press ✓. To discard changes and go back to the options menu, press X.




Set time: Use the + and − buttons to adjust each parameter. Use the OK button to move between parameters. When finished, press ✓. To discard changes and go back to the options menu, press X.

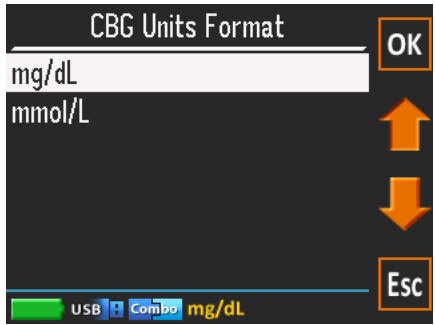
## Viewing Product Information

From the **Main Menu** in **Options** choose **Product Info**. The model and serial number are displayed.



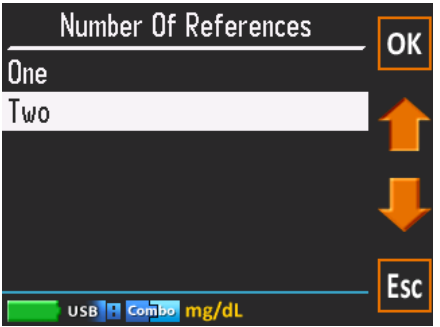
## Adjusting Capillarity Blood Glucose Units Format

Choose **CBG Units Format** from the **Main Menu, Options, User Settings**. Press the and buttons to adjust.



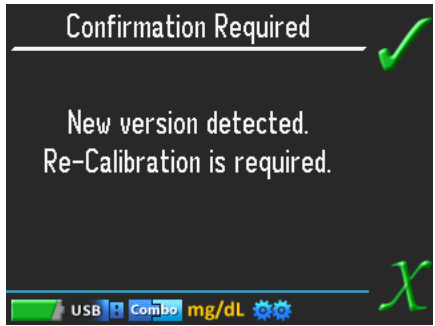
## Adjusting Number Of References for Calibration

**This feature is not applicable at the moment.**



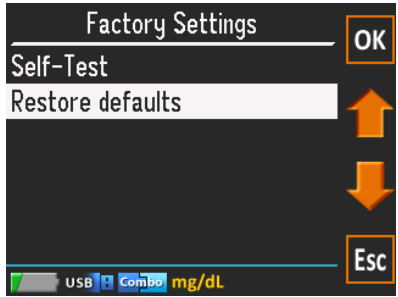
## Software Version Update:

Following software version upgrade the device should be recalibrated. For automatic recalibration please press the ✓ button.



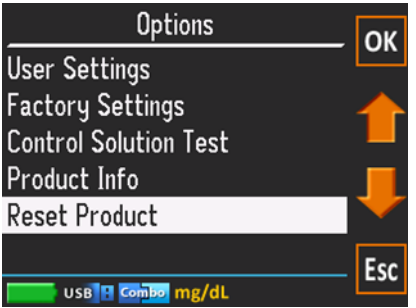
## Restoring Factory Defaults

Choose **Restore defaults** from the **Main Menu, Options, Factory Settings**. All user settings will be restored to factory default values. Measurement results history, Calibration data, Last measurement results and Clock setting will be cleared.



## SW Reset

Choose **Reset product** from the **Main Menu, Options**. The device will be reset.



# 3 Accuracy

The Non Invasive TensorTip Combo-Glucometer is the first of its kind in the world that is capable of estimating non-invasively capillary blood glucose. Because the measurement is performed without drawing blood it is important to choose an appropriate fingertip. In addition while performing the measurement you should relax and avoid any movement. Make sure you schedule measurement according to the calibration schedule. If the measurement fails we suggest that you try adding new point of calibration. Switching fingers is not recommended. Make sure that the fingertip is intact, sufficient warm and appropriately fits the chamber while avoiding excessive pressure on the finger tip.

As this is a completely new product you may occasionally experience difficulties in performing a reading. Please do not hesitate to report on

any malfunction. It is our duty to continuously improve the product and your assistance reporting on any problem encountered is welcome.

The non-invasive TensorTip Combo-Glucometer has been assessed in comparison with three well know home used invasive blood glucose meters and with the current combo test strips. The Combo-Glucometer error is about 20% relative with the references.

| **Ranges** | |
|---|---|
| Device Range: | 50-500 (mg/dL) |
| Tested Range | 70-440(mg/dL) |

## Comparing with Laboratory Results

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

### Before going to the lab

1. Perform a control solution test to make sure that the add-on device is working properly.
2. It is best to fast for at least eight (8) hours before doing comparison tests.
3. Take your Combo-Glucometer with you to the lab.

### While at the lab

1. Make sure that the measurement for both tests (the Combo-Glucometer test and the lab test) are taken and tested within 15 minutes of each other.
2. Wash your hands before measurement.
3. Never use your meter with blood that has been collected in a grey-top test tube.
4. Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication, or experienced stress *1. In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test *2. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a

high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

*REFERENCE*:

*1. Surwit, R.S., and Feinglos,M.N.: Diabetes Forecast (1988),April, 49-51.
*2. Sacks,D.B.:^Carbohydrates.^ Burtis, C.A.,and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry.Philadelphia:W.B. Saunders Company (1994), 959.

## Performance Characteristic for the Invasive Add-on

- Accuracy

Within ± 15 mg/dL (0.83 mmol/L) at glucose concentration < 75 mg/dL (4.2 mmol/L) and within 20%
glucose concentration >75 mg/dL (4.2 mmol/L).

- Precision

CVs (%) of intermediate precision and repeatability were less than 5%.
The device has been certified to meet the following standards:98/97/EC, IEC 60601-1, IEC 61010-1, IEC 60601-1-2, IEC 61326, and ISO 15197

# 4 Technical Information

## Technical Specifications

| | |
|---|---|
| Operating humidity | 10-80% |
| Device Operating temperature | 6°C – 45°C |
| LED Wavelength | 300 nm to 1200 nm |
| Luminous Power Emissions:<br>625 nm<br>Other Wavelengths | <br>Up to 10000mcd (millicandelas)<br>Up to 35mW/Sr (Milliwatts per Steridian) |
| Altitude | 2000m |

| | |
|---|---|
| Dimensions | 43.2mm x 47.65mm x 74mm (H x W x L). |
| Weight | 99.9gr |
| Battery | 740mAh 3.7V Li-Polymer |
| Power supply | FW733SM/05 class 2<br>Input 110-230AC<br>Output 0.7A , 5VDC |
| USB Cable | Micro USB |
| Disposal | Contact local authorities for the location of a waste collection center near you. |

## Device Labels

The following symbols are used throughout the TensorTip device labeling:

| | | | |
|---|---|---|---|
|  | Type BF | CE | This product fulfills the requirements of Directive 93/42/EEC on medical devices |
|  | Manufacturer |  | Dispose of device properly according to local regulations |
| | | EC REP | EC representative |
|  | Consult operating instructions |  | Caution |

## Troubleshooting

If you experience trouble with your device check the following table. If the problem persists have the device repaired by an authorized technician only.

| **Problem** | **Possible Cause** | **Solution** |
|---|---|---|
| Device will not turn on | Battery is discharged | Recharge the battery |

| Problem | Possible Cause | Solution |
|---|---|---|
| "Measurement failed" message appears during measurement | Finger Chamber Lens is dirty | Clean the Finger Chamber Lens. (See Cleaning the Finger Chamber Lens page 101) |
| | Fingertip is not properly inserted | Reinsert your finger as shown on page |
| | Fingertip is dirty oily or wet | Clean and dry your finger |
| | Fingernail is too long | Clip fingernail prior to use |

| Problem | Possible Cause | Solution |
|---|---|---|
| | Finger is injured or not intact | Use a different finger. |
| | Finger is too big or too thin or too small | |
| | Device moves during measurement | Do not move during measurement |
| | Device is not positioned properly | Position the device according to Figure 2 |
| | Fingertip temperature is too cold | Warm your measured finger prior to use |

| Problem | Possible Cause | Solution |
| --- | --- | --- |
| "Critical failure nnn" (nnn stands for the error id) | One or more of the product's hardware components have failed, and the device is not usable. | Contact authorized service |

| Problem | Possible Cause | Solution |
| --- | --- | --- |
| "Self-test error #Tnnn" during self-test | T001: The Finger Chamber was not sealed for light<br><br>T002-T020: optical unit failure | Make sure that the chamber is closed properly with the cover and run self-test again. If the error persists, contact authorized service.<br><br>Make sure the Finger Chamber Lens is clean (See Cleaning the Finger Chamber Lens page 101) and run self-test again. If the error persists, contact service |

| Problem | Possible Cause | Solution |
| --- | --- | --- |
| No response when the test strip is inserted into the strip slot | Device is turned off.<br>The module is not well connected.<br>The strip was inserted not in the right direction<br>Device is defective | Turn the device on.<br>Disconnect the module and reconnect it.<br>Remove the strip and re-insert it correctly<br>Contact authorized service. |

| Problem | Possible Cause | Solution |
|---|---|---|
| No response when the blood sample applied to the test strip | Blood sample is not sufficient.<br>The test strip is not detected/identified.<br>Device is defective | Repeat the test with sufficient blood sample and a new strip<br>Repeat the test with a new strip.<br>Contact authorized service. |

| Problem | Possible Cause | Solution |
| --- | --- | --- |
| A complexity in the calibration pattern was detected. Contact your distributor. | Values outside the device range were inserted | Please contact your Distributor. |

## Cleaning the Finger Chamber Lens

If the Finger Chamber Lens becomes dirty, it may not provide accurate results. Occasionally gently clean the Chamber Lens with a cotton swab moistened in alcohol (70%).

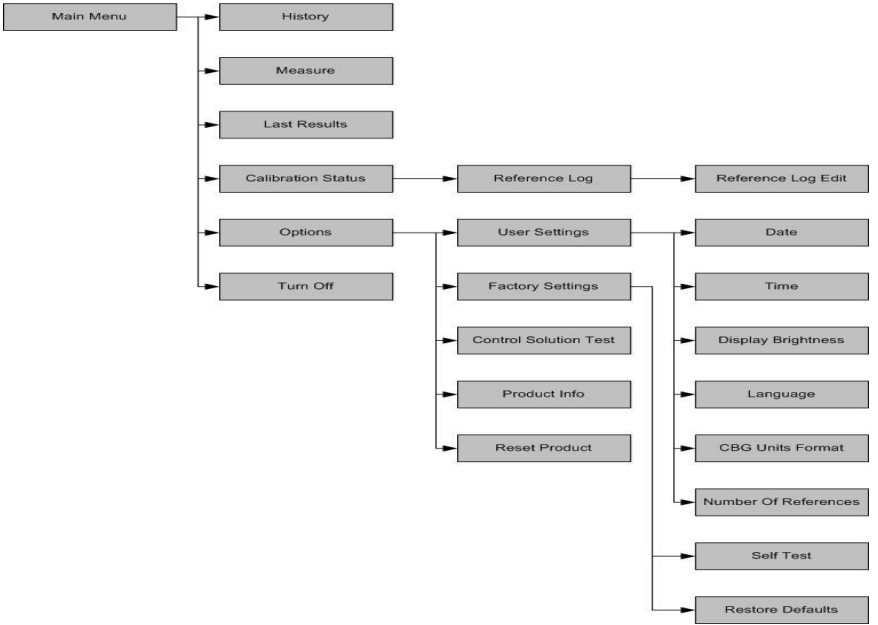
**Figure 3: Finger Chamber Lens Location**

**Caution**

Do not clean the Finger Chamber Lens with damp or abrasive cleaners, or solvents.

## HW Reset

Insert gently a pin into the hole on the chamber base to reset the hardware.


Main Menu
History
Measure
Last Results
Calibration Status
Reference Log
Reference Log Edit
Options
User Settings
Date
Turn Off
Factory Settings
Time
Control Solution Test
Display Brightness
Product Info
Language
Reset Product
CBG Units Format
Number Of References
Self Test
Restore Defaults

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