CNOGA

Seeing Beyond Imagination

TensorTip™ VSM

Vital Signs Monitor

User Manual

CNOGA Medical Ltd.
TensorTip™
VSM™
User's Guide
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For the latest User's Guide version, please enter our website (www.cnoga.com), support section, downloads subsection.

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1 Introduction

What is the TensorTip

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.

TensorTip is a family of non-invasive devices that enable quick and painless measurement of physiological parameters. The VSM™ is a member of the TensorTip family calibrated to measure heartbeat, blood pressure and optional blood oxygen saturation by simply inserting your finger into one compact and simple device.

The TensorTip-VSM is able to measure and display the following parameters:

Measure and Display	Graph Display*
BP *(Systolic and Diastolic)*	Peripheral Pulse Wave (PPW)
SpO2 *spot-check**	BP Waveform and BP Variation
Peripheral Pulse Rate (PPR)	TensorTip ECG is one side partial ECG information

* Optional – SpO2 and graphs are optional and vary according to the regulatory approval and the ordered device.

Warnings, Cautions and Notes

Cautions and Notes that used throughout this manual:

Caution

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

Note

Notes contain helpful information and tips

Safety Notes

- Read this user manual before using your TensorTip.
- Do not use the TensorTip on an injured or maimed 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 a sole diagnostic indicator.
- Do not look directly into the TensorTip Measurement Chamber.
- The device contains no user-serviceable parts. In case of a technical problem, only an authorized technician may repair the device.
- Do not drop the device. If the device dropped or physically damaged, discontinue use unless certified by CNOGA.

- The TensorTip should not be stored with common household waste products.
- Limit a measurement to up to 5 minutes at a time.
- The device not intended for use in the presence of water or flammable substances.
- The TensorTip device can be operated by external batteries module or by external USB power supply and is classified as Class II. It also classified as applied part Type BF (IEC 60601-1) with continuous operation

Indications for Use

The CNOGA Medical's Non-invasive TensorTip VSM is a small, lightweight, portable, device intended for measuring and display of BP (Systolic and Diastolic), Peripheral Pulse Rate (PPR), SpO_2 spot check and graphs*. Measurement performed on capillary fingertip tissue (other than the thumb). The left ring finger is the recommended site. The results of each measurement are stored in the system memory. The device intended for use in the home environment and as an additional support in clinics.

It intended for use by any person aged above 18 years old.

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* Optional – SpO2 and graphs are optional and vary according to the regulatory approval and the ordered device.

Important Notice

Caution

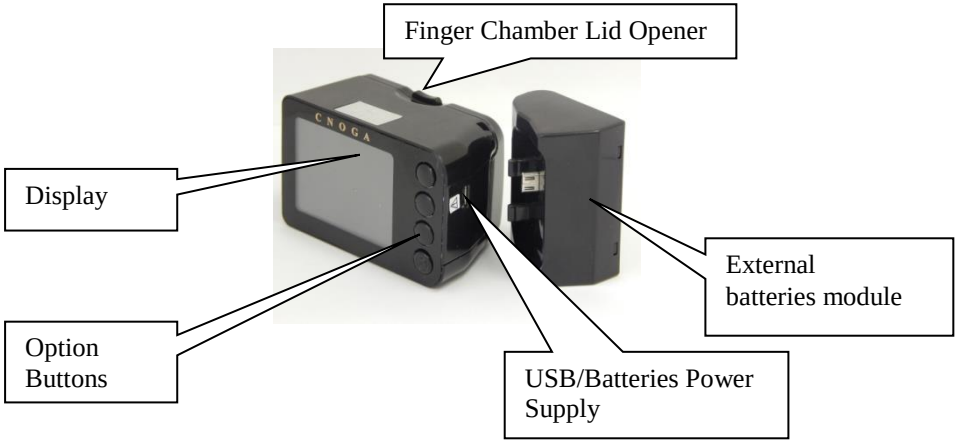
To avoid damaging the device, do not ever attempt to push your finger in or pull your finger out of the Finger Chamber with the lid closed. Always open the lid to insert or extract your finger

Inside the Box

TensorTip supplied with the following components:

- VSM™ device
- Stand/Finger Chamber cover
- Protective pouch
- Finger Chamber internal closure
- User Manual
- Plastic cover
- External Batteries module

TensorTip Components



The Option Buttons change functionality depending on the status of the device as displayed on the screen. An icon on the screen indicates the function of each button. Push the adjacent option button to select the desired function.

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-test performed.

2 Using the VSM

Turning the Device On and Off

Connect power supply or external batteries module.

TensorTip turns on automatically when you initiate a measurement by closing the lid with your finger inserted, and turns off automatically 30 seconds after the last time any button was pressed. During a reading, the device will not turn off. You can also manually turn the device on by holding the On/Off button ( ) for 3 seconds.

Time displayed by holding the On/Off button for one second.

Note

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

Icons

The VSM™ contains four buttons. These buttons change functionality depending on the status of the device and is displayed on the screen by an icon that indicates the function of each button.

The following icons will be displayed when appropriate:

	Back		History		Heart rate		Oxygen saturation
	Blood Pressure		Stop		Retry		Brightness
	External Battery Status		Next		Save Results		Scroll Up

	Accept		Reject		Progress indicator		Scroll Down
	Increase		Decrease		USB Connection		Inadequate Signal
	Switch display mode		Switch graph display mode		Measured tissue is cold		Measured tissue is hot

USB Power supply and Battery replacement.

If external batteries used:

1. Three AAA batteries are required for the device function, using CNOGA batteries module only (Figure 1)- supplied with the device.

Low-batteries icon will appear on the screen indicating that external batteries have exhausted their power and must be replaced.

2. Alternative small size battery module will be available.

Figure 1: Battery Module

If USB power supply used:

Use “medical” USB power supply only- USB A/M to Micro USB B/M 5 Pins Cable 1.5m Maximum Length.

Figure 2: USB Power Supply

Note

If the display is blank and the ⏺ *button does not turn the device on,the power source is not connected properly or the external batteries need to be replaced. Once the power source is reconnected and/or external batteries replaced, press the* ⏺ *button to turn the device on*.

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 has 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 52.

For instructions regarding setting the date and time, see "setting Date and Time", page 50.

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.

Performing a Measurement

Performing a measurement is simple: while in a sitting position, open the Finger Chamber Lid, insert your finger (see section 3 in measurement procedure- page 30), close the lid, and turn the screen towards you. The results will appear automatically. In order to start a new measurement follow the instructions set in paragraph 6 in the measurement procedure section and start from beginning.

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 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.
- Relax while performing a measurement.

- You should be in a sitting position with your elbow resting on a firm surface.
- Your wrist should be relaxed and the arm extended.
- The device should hang on the finger downwards below the heart level and slightly above the supporting surface. See Figure .
- Make sure that your fingernail clipped.
- If your fingertip is not intact, damaged or bandaged, use another finger (either your ring or index finger).
- Make sure the fingertip is clean and naturally moisturized.
- Make sure that the lid of the Finger Chamber closed properly and that your finger is firmly in place.

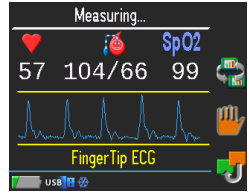
- Check that a pulse waveform displayed. If not, try cleaning and reinserting your finger.

Figure 3: Measuring Position

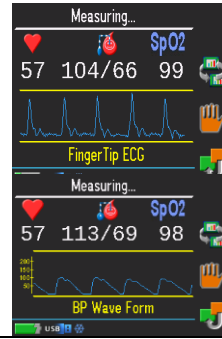
Measurement procedure

1. Before performing a measurement, make sure your fingernail clipped and then clean your fingertip using the finger wipe provided with your TensorTip. Dry your finger. Performing a measurement on a dirty or greasy fingertip may affect the results.	
2. Open the lid of the Finger Chamber by pushing the button. **Do not attempt to push your finger into the chamber without opening the lid**.	

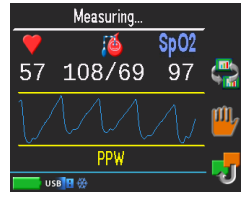
3. While holding the TensorTip with your right hand, insert the index, middle or ring finger (depending on which fits best) of your left hand with the bottom side of your finger in contact with the Chamber floor and touching the front of the Chamber. The fingertip should not be pushing the front of the chamber and should completely cover the Chamber Lens.	
4. Close the lid of the Finger Chamber.	
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.	

6. TensorTip will automatically turn on and results will be shown within seconds. Open the lid and withdraw your finger to end the measurement. The device will then automatically turn off after 30 seconds if no buttons are pressed. The measurement can be stopped at any time by pressing the button. To abort the measurement and return to the Main Menu, press the button.	

7. Switching Between Display Modes*:
During measurement, as well as after measurement has stopped, you can switch between the graphical displays modes. TensorTip can display graphs of either the FingerTip ECG Waveform, the Blood Pressure Waveform (BPW), the Peripheral Pulse Waveform (PPW) or the Blood Pressure Measurement Variation (BP - Variation), to switch between the display modes, press  .



* Optional – SpO2 and graphs are optional and vary according to the regulatory approval and the ordered device.

8. Remove and reinsert your finger to perform a new measurement.	

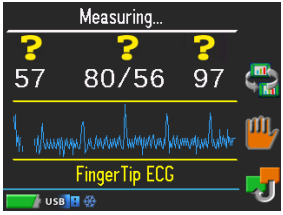
Caution

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

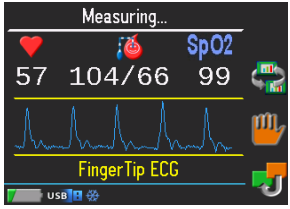
Make sure the device attached to your finger properly. If your finger is too small and does not fill the Finger Chamber, the device might fail to operate correctly.

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

- Important: Low blood perfusion in the fingertip may generate a weak signal, usually accompanied by the question mark as shown in the graph on the left picture (a), while picture (b) on the right represents a stable signal. The phenomena of low perfusion may occur when the fingertip is too cold. It suggested warming the fingertip in order to stimulate the blood circulation.



Picture (a)



Picture (b) *

* Optional – SpO2 and graphs are optional and vary according to the regulatory approval and the ordered device.

- Note: low blood pressure or low Spo2 might be a result of low perfusion in the fingertip.
- Warming the fingertip in order to stimulate the blood circulation can be achieved by casting your hand towards the ground, in this way larger amount of blood will flow to the fingers. In addition, you can rub your hands together.

Interpreting your Graphs*

Please note that the below graphs are for indication and description purposes only. The outline and scales of the graph will be as shown in below graphs.

- The following graphs represent the **average value of the changes** in the blood pressure over time. Picture 1 is to clarify the explanations.
- The blood pressure waveform is normalized between zero to Max_Systolic_Amplitude. Therefore, blood pressure sloop decreases to zero (scale value). Min Diastolic Amplitude scaled during each cycle to zero.

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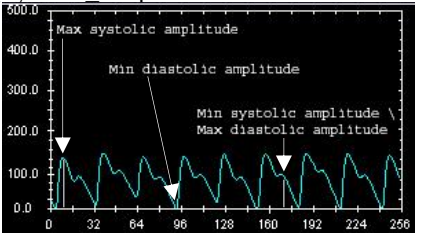
* Optional – SpO2 and graphs are optional and vary according to the regulatory approval and the ordered device.

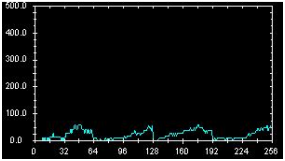
- Min_Diastolic_Amplitude > 0 (real value) since the blood volume in the blood vessels must be greater than zero otherwise the blood vessels would collapse. This basic volume of blood in the blood vessels generates the temporal average diastolic pressure.

- The systolic amplitude decreases from Max_Systolic_Amplitude until reaching a point on the graph slope denoted by Min_Systolic_Amplitude. This point also represents the Max_Diastolic_amplitude. From that point the amplitude continues to decrease until reaching Min_Diastolic_Amplitude. This point is normalized to zero so the whole graph is scaled between zero to Max_Systolic_Amplitude.

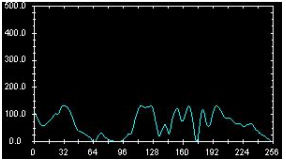
Picture (c)



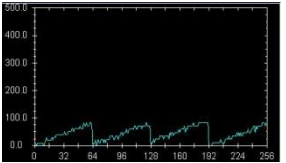
- Low perfusion of the blood in fingertip may have a disorder or low resolution waveform as in the following graphs (pictures (d), (e) and (f)) bellow. It is suggested to warm the fingertip by rubbing the fingertip.



Picture (d)

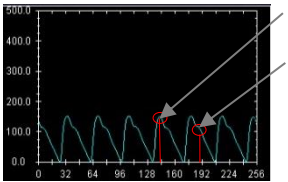


Picture (e)



Picture (f)

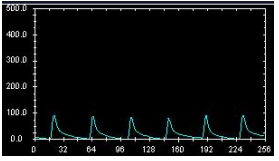
- In cases of relatively high systolic blood pressure and relatively high diastolic blood pressure, the graph may be seen as in the following picture (g).



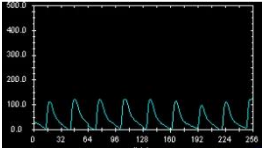
Picture (g)

- The following blood pressure waveform graphs (pictures (h) and (i)) may indicate that the stroke volume (or Cardiac Output) is relatively below normal.

Furthermore, picture (h) indicates that the diastolic pressure is relatively low while picture (i) indicates that the diastolic pressure is relatively normal. For more information, we suggest consulting your health physician.



Picture (h)



Picture (i)

The Valsalva maneuver

The Valsalva maneuver performed by moderately forceful attempted exhalation against a closed airway, usually done by closing the mouth, pinching the nose shut while pressing out as if blowing up a balloon.

The normal physiological response consists of four phases.

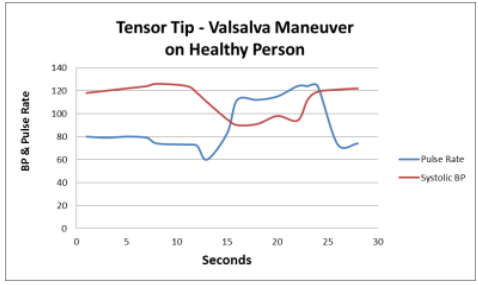
1. Initial blood pressure rise with peripheral pulse descends.
   On application of expiratory force, pressure rises inside the chest forcing blood out of the pulmonary circulation into the left atrium. This causes a mild rise in stroke volume.
2. Reduced venous return and compensation by pulse rate rise.
   Return of systemic blood to the heart is impeded by the pressure inside the chest. The output of the heart reduced and stroke volume falls. This occurs from 5 to about 14 seconds in the illustration. The fall in stroke volume reflexively causes blood vessels to constrict with some rise in pressure (15 to 20 seconds). During this time, the pulse rate increases (compensatory tachycardia).
3. Pressure release

The pressure on the chest released, allowing the pulmonary vessels and the aorta to re-expand. Venous blood can once more enter the chest and the heart, cardiac output begins to increase.

4. Return of cardiac output

   Blood return to the heart enhanced by the effect of entry of blood, which had been dammed back, causing a rapid increase in cardiac output (24 seconds on). The stroke volume usually rises above normal before returning to a normal level. With return of blood pressure, the pulse rate returns towards normal.

   Deviation from this response pattern signifies either abnormal heart function or abnormal autonomic nervous control of the heart.



Switching Between Display Modes*

During measurement, as well as after the measurement has stopped, you can switch between the graphical display modes. TensorTip can display graphs of either the FingerTip ECG Waveform, the Blood Pressure Waveform (BPW), the Peripheral Pulse Waveform (PPW) or the Blood Pressure Measurement Variation (BP - Variation). To switch between the displays modes, press  .

* Optional – SpO2 and graphs are optional and vary according to the regulatory approval and the ordered device.

Saving Measurement Results in History

TensorTip can keep the results of up to 100 measurements, saved in chronological order. To save the results of a measurement once it has been stopped, press  .

Viewing History

Viewing the measurement result history can be initiated either when a measurement has been stopped by pressing  , or by selecting **History** on the **Main Menu**. Once the **Result History** screen is displayed, press  and  to scroll up and down, and  to switch between the parameters being displayed in the result list (heart rate, SpO_2 or blood pressure).

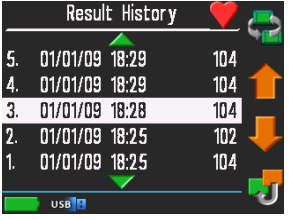


Figure 4: Result History

Viewing Last Results

On the **Main Menu,** choose **Last Results**. The previous last result will be displayed.

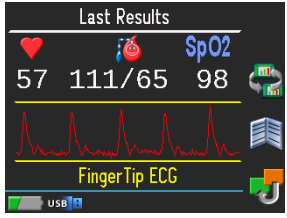


Figure 5: The Last Results Screen

Viewing Results over PC*

The user may connect the TensorTip to a PC using Cnoga isolated USB cable. Special driver from Cnoga is required to view and save results on a PC.

* Optional .

Adjusting Display Brightness

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

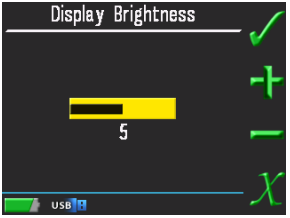
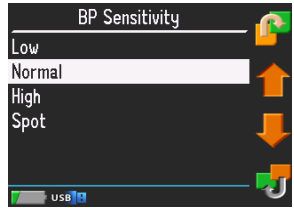


Figure 6: Brightness Screen

Adjusting Blood Pressure Sensitivity

Choose BP Sensitivity from the Main Menu, Options, User Settings.
Press the and buttons to adjust.



- Low sensitivity - continuously displayed results represent up to 30 seconds reading average.
- Normal sensitivity - continuously displayed results represent conditional change- automatic measurement.
- High sensitivity - continuously displayed results represent sufficiently close to bit to bit changes.
- Spot – the measurement is stopped when readings stabilize and a final result is displayed

Adjusting TensorTip Perfusion

You can adjust the blood perfusion by choosing TensorTip Perfusion from the Main Menu, Options, User Settings.
Press the  and  buttons to adjust.

- Low - the results will be adjusted to low perfusion situation.
- Normal - the results will be adjusted automatically by the device.
- High - the results will be adjusted to high perfusion situation.

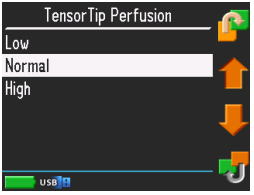
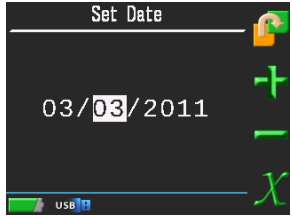
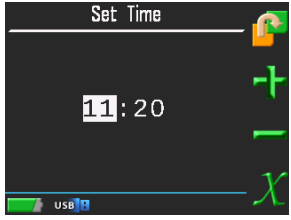


Figure 7: Perfusion

Setting Date and Time

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

Select	This Appears	To Adjust
Date		Use the + and − buttons to adjust each parameter. Use the button to move between parameters. When finished, press ✓. To discard changes and go back to the options menu, press X.

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

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**.**

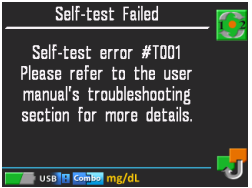
1. Extract your finger from the chamber.

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  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 64



Viewing Product Information

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

Figure 8: The Product Information Screen

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, Last measurement results and Clock setting will be cleared.

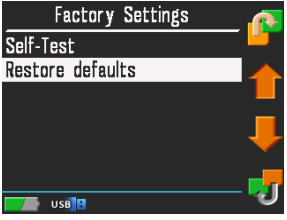


Figure 9: Restore Defaults Screen

SW Reset

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

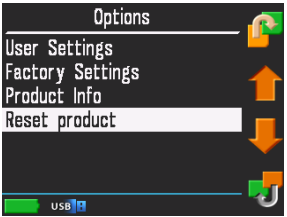


Figure 10: Reset Product Screen

3 Accuracy

The Non Invasive TensorTip VSM is the first device in the world that is capable of measuring Hemodynamic blood pressure without the use of air pumping. While performing the measurement you should be relaxed and avoid any movement. If the measurement fails, you may try inserting a different finger that best fits the chamber without excessive pressure on the fingertip.

The VSM has been assessed in correlation with automatic, manual Sphygmomanometers, in line arterial blood pressure and SaO2 Co-Oximeter in a study conducted on ambulatory volunteers. The precision of the VSM was compared between the closest value in the temporarily blood pressure interval and the reference measurement. The VSM standard deviation is relative to the standard deviation of the reference device:

Marker	**Ranges**	**%MSER** (Mean Square Error)	**Data Display Refreshment**
Blood Pressure Systolic	Device Range: 90-240 (mmHg) Tested Range: 90-180(mmHg)	< 10%	Every second
Blood Pressure Diastolic	Device Range: 30-130 (mmHg) Tested Range: 46-97(mmHg)	< 10%	Every second
Oxygen Saturation	Device Range: 25 -100 (%) Tested Range: 70-100 (%)	< 5%	Every second

4 Technical Information

Technical Specifications

Operating humidity	10-80%
Device Operating temperature	$6^{o}C – 45^{o}C$
LED Wavelength	600 nm < Wavelengths < 1100 nm
Luminous Power Emission 625nm Other wavelengths	 Up to 10000mcd (Millicandelas) Up to 35mW/SR (Milliwatts per Steradian)

Altitude	2000m
Dimensions	43.2mm x 47.65mm x 74mm (H x W x L).
Weight	109 gr
Battery	3 AAA batteries
USB Cable	Micro USB
Disposal	Contact local authorities for the location of a waste collection center near you.

Device Labels

The following symbols used throughout the TensorTip device labeling:

	Type BF			This product fulfills the requirements of Directive 93/42/EEC on medical devices
	Manufacturer			Dispose of device properly according to local regulations
	Date of Manufacture			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 checked by an authorized technician only.

Problem	**Possible Cause**	**Solution**
Device will not turn on	There are two possible reasons: 1. Power source (power supply or external batteries) not connected properly. 2. Replacement of external batteries is necessary	1. Insure connection of power source. 2. Replace external batteries.

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 70)
	Fingertip is not properly inserted	Reinsert your finger as shown on page 28
	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
	Fingertip temperature is too low	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 our service department

Problem	Possible Cause	Solution
"Self-test error #Tnnn" during self-test	T001: The Finger Chamber was not sealed for light T002-T020: optical unit failure T002-T010: optical unit failure	Make sure that the chamber is closed properly with the cover and run self-test again. If the error persists, contact our service department. Make sure the Finger Chamber Lens is clean (See Cleaning the Finger Chamber Lens page 70) and run self-test again. If the error persists, contact our service department

Problem	Possible Cause	Solution
 Inadequate Signal	Finger is not inserted properly or is not suitable. Low perfusion of blood	Use appropriate finger. Try ring or index finger. Finger is too cold. Warm your finger. If your finger is warm and the sing  is continues being showed, please visit your physician.

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%).

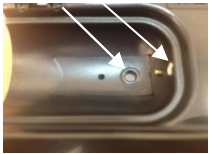
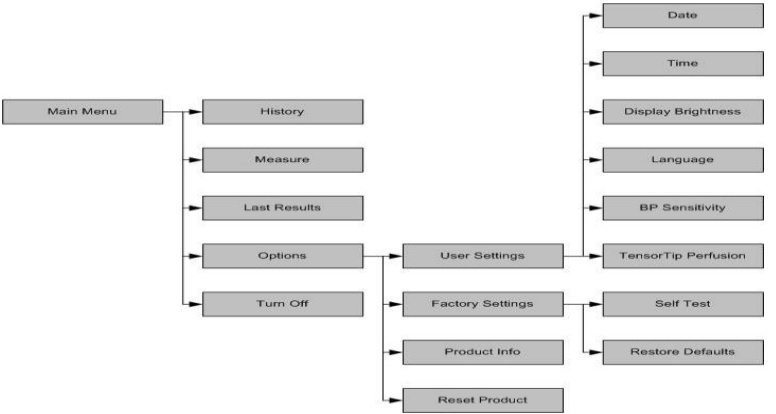


Figure 11: Finger Chamber Lens Location

Caution

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

5 Menus


Main Menu
History
Measure
Last Results
Options
Turn Off
User Settings
Factory Settings
Product Info
Reset Product
Date
Time
Display Brightness
Language
BP Sensitivity
TensorTip Perfusion
Self Test
Restore Defaults

6 Contact Information

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