CNOGA MEDICAL
Seeing Beyond Imagination

TENSORTIP

MTX

MATRIX

User Manual

CNOGA MEDICAL
Seeing Beyond Imagination

CNOGA

Seeing Beyond Imagination

TensorTip™ MTX

Matrix

User Manual

CNOGA Medical Ltd.
TensorTip™
MTX™
User's Guide
Revised: May 2019
Document #: MTX 1021

CE 0482

Contact Cnoga Medical Ltd at: E-mail: info@cnoga.com

For the latest User's Guide version, please enter our website (www.cnoga.com), support section, downloads subsection.
PA020310

EC REP

Europe
MedNet GmbH
Borkstrasse 10
48163 Muenster • Germany

Israel
5 Tarshish St. North Industrial Park,
Caesarea, 3088900, POB 3188
Tel: +972 4 6361080, Fax: +972 4

Table of Contents

1. Introduction

1.1 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 optimum use of the device.

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

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

Numeric Display	Graph Display
Hemodynamics: •Peripheral Pulse Rate (PPR) •BP (Trending - *Systolic and Diastolic*) •Cardiac Output • SV •MAP	• Optical cardio gram • BP Waveform and Variation • Peripheral Pulse wave (PPW)
Hematology: •Hemoglobin • Hematocrit •RBC •BV	
Blood gases: •SpO_2 spot-check •partial CO_2 pressure •partial O_2 pressure •pH •O_2 • CO_2	
Biochemistry: •Hemoglobin A_1C*	

*Optional

Note

The parameters vary according to the regulatory approval and the ordered device as indicated on the device packaging. This user manual describes all the parameters.

Warnings, Cautions and Notes

Cautions and Notes that are 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.

1.2 Safety Notes

- Read this user manual before using your TensorTip.
- Do not use the TensorTip on an injured finger or a finger with an open wound.
- 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. Please consult your doctor in case of any numerical or graphical results deviating from your normal results.
- The device contains no user-serviceable parts. In case of a technical problem, only an authorized technician is authorized to 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 and cleaning products.
- The device not intended for use in the presence of water or flammable substances.
- The TensorTip device is classified as an internally powered device when battery operated and Class II when mains powered. It also classified for continuous operation, with a Type BF Applied Part.
- The use of RF (Radio frequency) in this product is licensed for use by the FCC, CE, Japan, SRRC, Anatel. For further information on any potential restriction, refer to documentation on BLE usage by the relevant authority.

1.3 Indications for Use

The CNOGA Medical's non-invasive TensorTip MTX is a small, lightweight, portable, device intended for measuring and display of BP trending (Systolic and Diastolic) and SpO_2 spot check, Hemoglobin, Peripheral Pulse Rate (PPR), PCO_2, PO_2, MAP, HCT, CO, pH, BV, Peripheral Pulse Wave (PPW), graphs of BP variation and additional Hemodynamic parameters and graphs. Measurements are 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.

Caution

Please note, that the CNOGA Medical's Non-invasive TensorTip MTX does not and cannot replace professional medical advice.

1.4 Important Notice

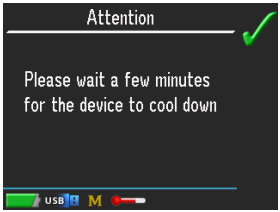
Caution

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.

Caution

Limit a measurement to up to 10 minutes at a time.

When temperature reaches 40°C in the finger chamber, the measurement will be stopped automatically, and the following message will appear.



Caution

Do not look directly into the TensorTip Measurement Chamber.

Do not operate the unit in the presence of electromagnetic interference. Interference may be caused by electrosurgery, diathermy, magnetic resonance imaging or other equipment.

Portable and mobile RF (Radio Frequency) communications equipment may affect operation of this device. In case of interference, move the device to a location away from the source of interference.

Do not use the device in an oxygen rich environment.

1.5 Inside the Box

TensorTip is supplied with the following components:

- MTX™ device
- Battery charger - Input: 100v~-240v~, 50Hz – 60Hz
  - DC Output: 5v / 1300mA
- Stand/Finger Chamber cover
- Protective pouch
- Self-Test Arc
- User Manual

1.6 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.

1.7 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 self-test ARC inside the chamber after self-test was performed.
- Between measurements cover with the finger chamber with the finger chamber cover.

2. Using the MTX

2.1 Turning the Device On and Off

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 is pressed. During a reading, the device will not turn off. You can also manually turn the device on by pressing the On/Off button () for 3 seconds.

Press the On/Off button for one second to display the time and battery status.

Note

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

2.2 Icons

The MTX™ 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 are content dependent and displayed according to the status of the device:

	Back		History		Heart rate		Oxygen saturation
	Blood Pressure		CO_2 Partial Pressure		O_2 Partial Pressure		Mean Arterial Pressure
	Capillary pH		Cardiac Output		Blood Viscosity		Hematocrit
	Red Blood Cell Count		Stroke Volume		Oxygen		Carbon Dioxide
	Hemoglobin		Switch Page		Stop		Retry

	Brightness		Battery Status		Next		Save Results
	Scroll Up		Accept		Reject		Progress indicator
	Scroll Down		Increase		Decrease		USB Connection
	Inadequate Signal		Switch display mode		Switch graphs display mode		Measured tissue is cold
	Measured tissue is hot		Low battery indicator		Large Arm Cuff		Medium Arm cuff
	Small Arm Cuff		Paired to Cnoga host device		Optical Cardiogram		High temperature

2.3 Charging and Recharging TensorTip

When the battery symbol indicates  , the rechargeable battery has exhausted its power and you must recharge your TensorTip.

To recharge the TensorTip, plug the connector of the USB cable into your TensorTip (see figure below). Leave the TensorTip plugged in until the battery icon indicates that it is full and the “Battery charging complete” message appears on the screen. In case of recharging the battery from a PC use only the CNOGA Isolated USB cable.

Note

If the display is blank and the button does not turn the device on, the battery is discharged and recharging is necessary.

Once the battery is charged, press the button to turn the device on.

Caution

Even if the device is not in use, the battery must be charged every three months. Not charging the battery at least once every three months may result in damage to the battery.

Note

The user cannot remove the battery.

The battery is not user-replaceable and can be replaced only by CNOGA - authorized technicians only.

Caution

DO NOT dispose of batteries in fire as this can cause them to explode.

2.4 First-time Operation

Before first use, fully charge the battery.

The first time TensorTip is activated, please conduct the following steps:

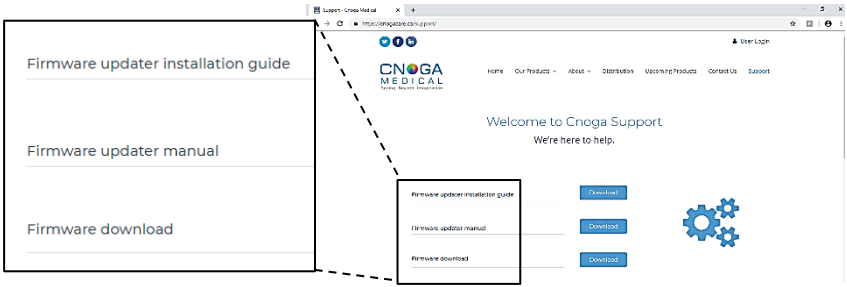
1. Check for firmware updates (see Check for Updates section on page 25)
2. Set language preference (see Language selection section on page 27)
3. Set date and time (see Setting Date and Time section on page 28)
4. Run device's self-test (see Device Self-Test on page 30)

Note

If the self-test is not completed successfully or if the date and time are not set, TensorTip will not allow normal operation.

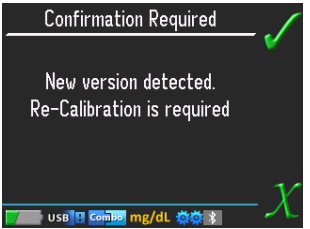
2.5 Check for Updates

Download an updated Cnoga's Firmware and Firmware updater installation guide and manual from the following address: https://cnogacare.co/support/. Follow the installation guide to perform a successful firmware update.



Following firmware version upgrade the device will ask for automatic recalibration.

For automatic recalibration please press the ✓ button.



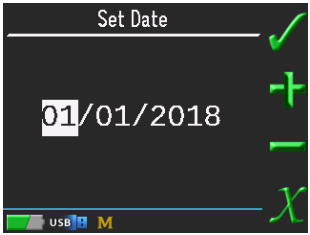
Check regularly for new updates.

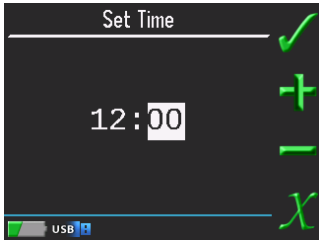
2.6 Language selection

The TensorTip is a multilingual device that allows the user to select the desired language of operation. The language will be set up as an initial setting and can be modified by the user any time during the device lifecycle. To change operating language, choose Language from the Main Menu, Options, User Settings menu, then press the and buttons to select desired language.

2.7 Setting Date and Time

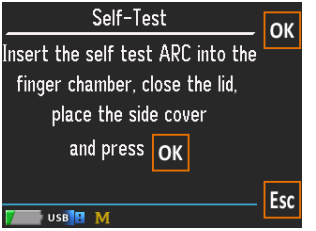
Access Set Date and Time from **Main Menu**, **Options**, **User Settings**.

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

2.8 Device 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, and 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 measurements or other operations 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 chamber.

2. Insert the black plastic self-test arc into the chamber so that the small pin on the arc enters the small hole in the chamber center.

Note

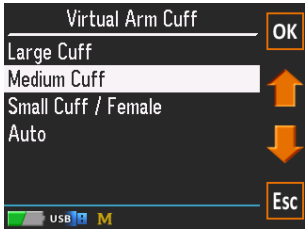
Please keep the ARC for future use

3. Close the Lid and then close the chamber entrance using the "finger chamber cover".
4. Press the button near the OK icon.
5. The screen will turn red, green and blue accompanied by tones (in some models).
6. The progress indicator appears.
7. A successful self-test or failure message appears. If the self-test failed, see page 60.

2.9 Virtual Arm Cuff

Before initiating a measurement, please adjust the Virtual Arm Cuff, choosing this option out of the Main Menu (see figure below).
Press the and buttons to adjust.

- Large - use for male with cold finger temperature, male/female with high body BMI or male/female suspected with high blood pressure
- Medium - use for male with normal body BMI or female with cold finger temperature.
- Small - use for small body BMI e.g. female
- Auto - the device will adjust the results automatically.



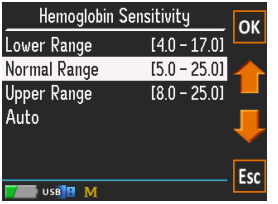
2.10 Adjusting Hemoglobin Sensitivity

For home users the default option is Normal range [5…25]

You should adjust the Hemoglobin Sensitivity in any of the following cases, choosing this option out of the Main Menu.

Press the  and  buttons to adjust.

- Lower Range [4…17] - use in case of suspected blood loss, intensive care, blood transfusion, or any case which requires high resolution of the lower hemoglobin range.
- Normal range [5…25] - default option for home users.
- Upper range [8…25] - use in case of suspected polycythemia, severe dehydration, or any case which requires high resolution of the upper hemoglobin range.



- Auto - can be used for home users and in cases not included in the above sections.

2.11 Performing a 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 (see figure on next page). Results will appear automatically.

Note

To start a new measurement, adjust the virtual arm cuff as described on page 33 and follow the instructions in Step 6 on page 40.

2.11.1 Tips for performing a successful measurement

Please keep in mind the following points while performing the measurement:

- Do not perform measurement when your finger is cold.
- Do not perform measurement after physical exercise. Make sure your heart rate 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 below.
- Make sure that your fingernail is clipped.
- If your fingertip is not intact, damaged or bandaged, use another finger (either your ring or index finger).

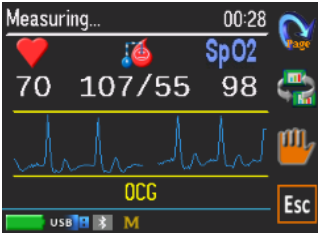
2.12 Measurement procedure

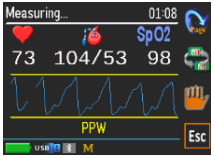
1. Before performing a measurement, make sure your fingernail is clipped and then clean your fingertip and dry your finger. Performing a measurement on a dirty or greasy fingertip may affect the results.	
2. Open the lid of the Finger Chamber by pushing the button. **Do not attempt to push your finger 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.

   Please note to squeeze the fingertip towards the end of the tip in order to circulate and inject more blood into the fingertip. This action will assist to have more adequate reading. Of course, this action shall not replace cleaning and warming the finger. It is

an additional operation ensuring better reading, particular when the new algorithm is calculating the potential vessel resistance	
4. Close the lid of the Finger Chamber.	
5. Turn your hand so that TensorTip is facing you. Hold the device 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 are displayed within seconds displaying time duration of measurement. 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 Esc button.	

7. To switch between the parameters pages, press . To switch between the graphical displays modes, press  .	
8. Remove and reinsert your finger to perform a new measurement.	

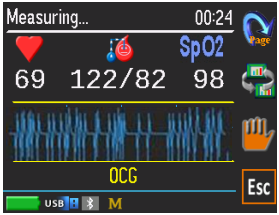
Caution

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.

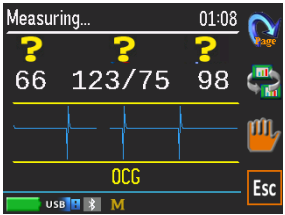
Make sure that your finger is properly placed in the device. If your finger is too small and does not fill the Finger Chamber, the device might fail to operate correctly.

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

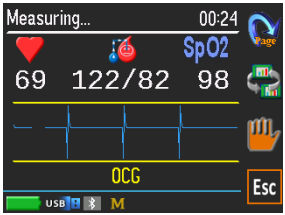
Important: If the graphical display shows noisy signal (A) or the parameters symbols are switched to question marks (B), the measurement should be repeated following the instructions under Technical Information → Troubleshooting section on page 59. Figure C represents stable signal and measurement.



A



B



C

Switching Between Display Modes

During measurement, as well as after the measurement has stopped, you can switch between the graphical display modes and between parameters pages. TensorTip can display graphs of either the FingerTip OCG 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  .

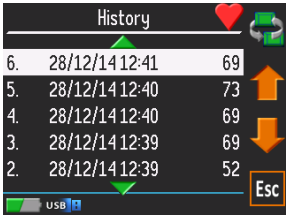
2.13 Saving Measurement Results in History

TensorTip can keep the results of up to 500 measurements, saved in chronological order. To save the results of a measurement once it has been stopped, press  .

3. Optional Procedures

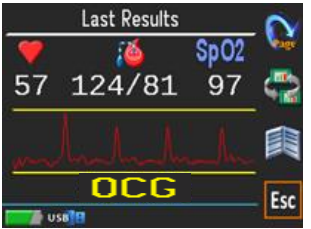
3.1 Viewing History

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 (see figure below), press and to scroll up and down, and to switch between the parameters being displayed in the result list.



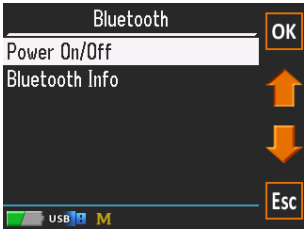
3.2 Viewing Last Results

On the **Main Menu,** choose **Last Results**. The previous last result is displayed (figure below).



3.3 Bluetooth (BLE) Module

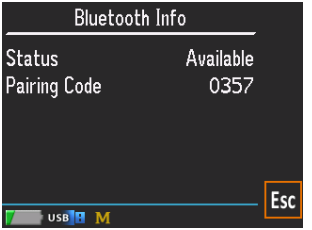
The BLE connection function of the TensorTip device is automatically in the device.
You can turn ON/OFF BLE manually by choosing this option out of the user settings (see **A** below).



A

3.4 Bluetooth (BLE) Info

In BLE info you can see the BLE status:



B

- OFF- BLE module is turned OFF.
- Available- BLE module is turned ON and ready for connection.
- Connected- While connected the status will also be seen in the status bar which will indicate pairing to CNOGA host device by the icon.
- Pairing code- during connection a pairing code indicated in BLE info section will be requested by the APP (see **B** above).

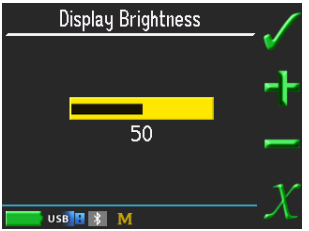
For CNOGA_APP information please contact your CNOGA distributor.

Caution

The content available through the TensorTip MTX and its accessory Apps, is for informational and educational purposes only and is not a substitute for the professional judgment of a health care professional in diagnosing and treating patients. Cnoga does not, through TensorTip MTX, provide medical advice, nor does it provide medical prescriptions, treatments, or diagnostic services.

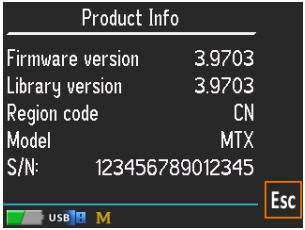
3.5 Adjusting Display Brightness

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



3.6 Viewing Product Information

From the **Main Menu** in **Options** choose **Product Info**. The model and serial numbers are displayed (see figure below).

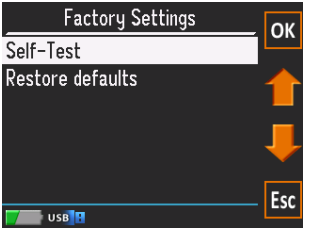


3.7 Restoring Factory Defaults

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

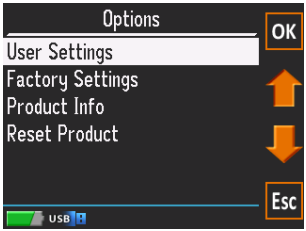
Caution

Restoring the device to factory default will delete all measurements stored on the device.



3.8 Software Reset

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



Note

*Performing Software Reset will **NOT** delete measurements stored on the device.*

4. Technical Information

4.1 Technical Specifications

Operating humidity	10-80%
Device Operating temperature	5°C – 40°C
Storage condition	5°C-25°C with no direct sunlight, <60% humidity, stored in closed boxes without access to dust and dirt. finger chamber should be covered by designated rubber cover and the device is "standing" on it.
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	99.9gr
Battery	Li-Polymer: PL802045-670mAH- Newsun, LCTV802045- LOWC Technology Co.
Battery service life	Six months

Power supply	FW7333SM/05 - Input: 100V to 240V; 50-60Hz - Output: 5VDC, 1300mA FW8002MUSB/05 - Input:100Vto240V;50-60Hz - Output: 5VDC, 1400mA
Service life of the device	One year
Service life of parts and accessories	One year
USB Cable	Micro USB
Disposal	Contact local authorities for the location of a waste collection center near you.
IP classification	IP22

4.2 Device Labels

The following symbols 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
	Consult operating instructions	EC REP	EC representative

Note

At the end of its useful life, the product should be disposed of in accordance with local regulations covering disposal of electronic products.

Caution

The device must be powered from mains only by dedicated power supplies, which are provided with the device and/or certified by CNOGA distributers.

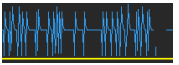
4.3 Troubleshooting

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	Battery is discharged	Recharge the battery
"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
"Measurement failed" message appears during measurement	Finger Chamber Lens is dirty	Clean the Finger Chamber Lens. (See Cleaning the Finger Chamber Lens, page 65)
	Fingertip is not properly inserted	Reinsert your finger as shown on page 38
	Fingertip is dirty oily or wet	Clean and dry your finger
	Fingernail is too long	Clip fingernail prior to use

	Finger is injured or not intact	Use a different finger
	Finger is too big or too thin or too small	
	Device was moved during measurement	Do not move during measurement
	Device is not positioned properly	Position the device according to “Performing a Measurement” page 35
	Fingertip temperature is too low	Warm your measured finger prior to use

 Inadequate Signal or Noisy signal 		
	Finger is not inserted properly or is not suitable.	Remove your finger and insert again. Use different finger. Try ring or index finger. Check that arm cuff is correctly defined.
	Low perfusion of blood.	Finger is too cold. Warm your fingertip to stimulate the blood circulation and start measurement again.
		If your finger is properly positioned and warm and the Inadequate or Noisy Signal continue to appear, perform the measurement again. If this situation repeats itself, consult your doctor.

A beep sound is heard	Finger movement during measurement	Remove your finger and perform measurement again.
	Bad quality of the signal	

"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, ` 65) and run self-test again. If the error persists, contact our service department.

4.4 Cleaning the Finger Chamber Lens

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

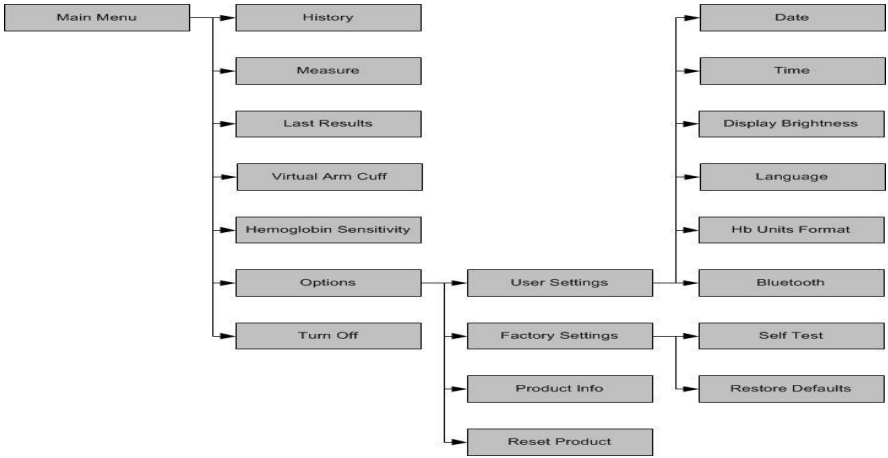
Caution

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

4.5 Hardware Reset

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

4.6 Menus


Main Menu
History
Measure
Last Results
Virtual Arm Cuff
Hemoglobin Sensitivity
Options
Turn Off
User Settings
Factory Settings
Product Info
Reset Product
Date
Time
Display Brightness
Language
Hb Units Format
Bluetooth
Self Test
Restore Defaults

Caution

- The CNOGA Medical's Non-invasive TensorTip MTX is not a remote diagnostic tool. Any decision made or action taken by you based on the services or its outputs are at your sole responsibility and liability, including the sharing of any information by you with a third-party healthcare professional.
- The use of TensorTip MTX, does not establish a physician-patient relationship.
- If you have any concerns or questions about your health, you should always consult with a physician or other healthcare professional.

5. Appendixes

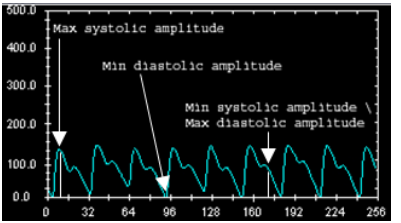
5.1 Interpreting your Graphs

Caution

Do not use the device as a sole diagnostic indicator. Please consult your doctor in case of any numerical or graphical results deviating from your normal results.

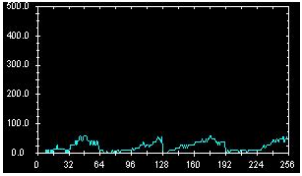
Please note that the below graphs are for illustration purposes only.
The outline and scales of the graph will be as shown in below graphs.

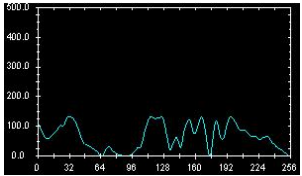
- The following graphs represent the **average value of the changes** in the blood pressure over time. See figure below for additional explanations.
- The blood pressure waveform is normalized between zero to Max_Systolic_Amplitude. Therefore, the blood pressure slope decreases to zero (scale value). Min Diastolic Amplitude scaled during each cycle to zero.
- 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.

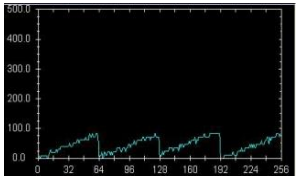


- The systolic amplitude decreases from Max_Systolic_Amplitude until reaching a point on the graph slope denoted by Min_Systolic_Amplitude. This point also represents the Max_Diastolic_amplitude. From that point the amplitude continues to decrease until reaching Min_Diastolic_Amplitude. This point is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

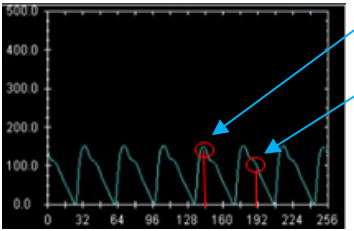
- Low perfusion of the blood in fingertip may have a disorder or low resolution waveform as in the following graphs on the figures below. It is suggested to warm the fingertip by rubbing it.



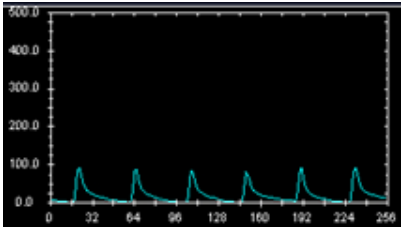




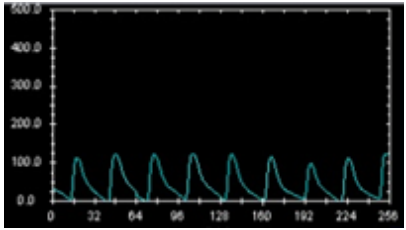
- In cases of relatively high systolic blood pressure and relatively high diastolic blood pressure, the graph appears as in the figure below.



- The following blood pressure waveform graphs (figures below) may indicate that the stroke volume (or Cardiac Output) is relatively below normal. (A) may indicate that the diastolic pressure is relatively low while (B) may indicate that the diastolic pressure is relatively normal. For more information, we suggest consulting your physician.



A



B

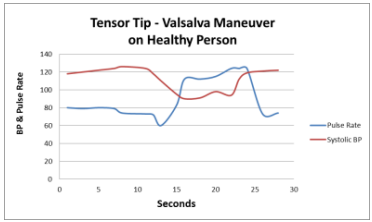
5.2 The Valsalva maneuver

The Valsalva maneuver is 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 a 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 is 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.



5.3 Accuracy

The MTX was assessed in a study conducted with marketed reference devices and handheld oximeters. Following are the accuracy values:

Parameter	Ranges	Average accuracy
Blood Pressure Systolic	Device Range: 50-300 (mmHg) Tested Range: 106-171 (mmHg)	Within ±8 mmHg
Blood Pressure Diastolic	Device Range: 30-130 (mmHg) Tested Range: 46-97 (mmHg)	Within ±8 mmHg
Oxygen Saturation	Device Range: 60 -100 (%) Tested Range: 66-100 (%)	Within ±4%
PPR	Device Range: 30-200 Tested Range: 49-12	Within ±5%

Parameter	Ranges	Average accuracy
Hemoglobin	Device Range: 2 - 25 (g\dl) Tested Range: 7.2-19 (g\dl)	Within ±1 g/dL
pO_2	Device Range: 10-300 (mmHg) Tested Range: 35-141 (mmHg)	Within ±6 mmHg
pCO_2	Device Range: 20-150 (mmHg) Tested Range: 27-49.5 (mmHg)	Within ±6 mmHg
Cardiac Output	Device Range: 0.1-25 (L/min) Tested Range: 1.57-8.7 (L/min)	Within ±27%
MAP	Device Range: 40-185 Tested Range: 45-116	Within ±8 mmHg

Parameter	Ranges	Average accuracy
HCT	Device Range: 10-70 (%) Tested Range: 21-55.2 (%)	Within ±6%
pH	Device Range: 6.5-7.9 Tested Range: 7.22-7.57	Within ±0.04 pH units
RBC	Device Range: 1-10 (ml\µL) Tested Range: 2-6.47 (ml\µL)	Within ±6%
O_2	Device Range: 5-50 (ml\dL) Tested Range: 11.2-23.8 (ml\dL)	Within ±5 (ml/dL)
CO_2	Device Range: 10-130 (mmol/L) Tested Range: 20.6-34.1 (mmol/L)	Within ±7.5 (ml/dL)
SV	Device Range: 10-300 (ml) Tested Range: 23-113 (ml)	Within ±27%

Contact Information

Cnoga Medical LTD.
5 Tarshish St. North Industrial
Park, Caesarea , 3088900,
P.O.B. 3188. Israel.
Tel: +972 4 6361080
Fax: +972 4 6361321
www.cnoga.com
E mail: info@cnoga.com

Europe
MedNet GmbH
Borkstrasse 10
48163 Muenster • Germany

PA020310, 22.05.2019, V.21