

TENSIOWin

Instruction for use

Software on Windows 10 or 11 operating systems. Used for operating Arteriograph24, TensioDay and TensioDay Plus devices

Please read the instruction for use carefully before the first use!

In addition to the user manual of the TensioWin software, **please also read the user manual of the devices operated with the help of the TensioWin software** (Arteriograph24, TensioDay and TensioDay Plus) carefully!

PC software

TensioMed[®] TensioWin-03v10-00 Revised: 03-04-2024

TensioWin user software

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1. Introduction and the intended use of the TensioWin software

The TensioWin software is an essential part of the TensioDay, TensioDay Plus and Arteriograph24 portable ambulatory devices. These devices can only be operated by this software with a medical purpose. The software itself, however, is **not** a medical device. The TensioWin software cannot be used on its own, it can only be used in conjunction with the mentioned instruments. The intended use of the TensioWin software is valid only together with the intended use of the particular device which the TensioWin software is used to operate.

TensioWin software is explicitly designed for professional (clinical) use and not for home use.

In the international medical field, the standard language is English, and the doctors communicate in English internationally. Thus, we identified the language requirements, and found English to be the proper international language for the markets of all EU member states. Furthermore, execution of multiple translations would result in a higher risk factor of ambiguous information due to unique linguistic properties of different languages. Even the best translation could result in misunderstandings of medical terms.

The function of the TensioWin software is to send the setup protocol and program the device, as required for the operation of the above-mentioned instruments. Furthermore, to read out the measured data from the devices into a computer, where the TensioWin software provides the measured data in a structured way.

The intended use of the operated devices:

Arteriograph24: The Arteriograph24[™] device measures the brachial blood pressure, the heart rate, and the arterial function parameters intermittently through 24 to 72 hours in 12-hour increments.

The measurements are performed non-invasively using a brachial cuff.

The device with its adherent TensioWin software provides the values of brachial blood pressure, heart rate and several arterial function parameters. It is plausible to use on those patients, where the information about aortic blood pressure and other arterial function parameters are required, but according to the physician's opinion, the risk of measuring these parameters by catheter and other invasive methods are higher than the benefit gained by this knowledge.

The Arteriograph24 is a **multiple-use device**. It cannot be connected to any other instrument.

The Arteriograph24 is a professional medical instrument and cannot be used in a home environment, i.e., patients cannot use it on their own. The assessment of the measurement results requires extensive **medical knowledge**.

TensioDay: The TensioDay[™] device measures the brachial blood pressure and the heart rate intermittently through 24 to 72 hours in 12-hour increments.

The measurements are performed non-invasively using a brachial cuff.

The device with its adherent TensioWin software provides the values of brachial blood pressure parameters and heart rate.



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The TensioDay is a **multiple use device**. It cannot be connected to any other instrument.

The TensioDay is a professional medical instrument and cannot be used in a home environment, i.e., patients cannot use it on their own.

TensioDay Plus: The TensioDay Plus[™] device measures the brachial blood pressure, the heart rate, and the central systolic blood pressure intermittently through 24 to 72 hours in 12-hour increments.

The measurements are performed non-invasively using a brachial cuff.

The device with its adherent TensioWin software provides the values of brachial blood pressure, heart rate and central systolic blood pressure. It is plausible to use on those patients, where the information about aortic blood pressure is desired, but according to the physician's opinion, the risk of measuring these parameters by catheter and other invasive methods are higher than the benefit gained by knowing these parameters.

The TensioDay Plus is a **multiple use device**. It cannot be connected to any other instrument.

The TensioDay Plus is a professional medical instrument and cannot be used in a home environment, i.e., patients cannot use it on their own. The assessment of the measurement results requires extensive **medical knowledge**.

The communication is via Bluetooth[®] wireless data transfer between the devices and the PC.

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Every effort has been made to ensure that the information in this manual is accurate.

TensioWin[™] is an unregistered trademark of TensioMed Ltd.

Other company and product names mentioned herein may be trademarks of their respective companies.

2. Contents of the manual

This manual helps you in setting up and starting to use the TensioWin software.



Attention! Please, read this user manual carefully before the first use.

3. The TensioWin software

Preliminary information about TensioWin software

The TensioWin software is a Windows-based software.

Developer data and contact information

The developer of TensioWin software is:

TensioMed Ltd. Cziráki Street 26-32 Building A, 44/b Budapest H-1163 Hungary Phone: +36 70 886 7337 +36 20 258 6369 Website: www.tensiomed.com E-mail: info@tensiomed.com

3.1 Installation and setup of the TensioWin software

Minimum system requirements

- Minimum configuration: Intel Pentium PC, 2GB memory, 3GB available HDD capacity, minimum 1024*768 screen resolution
- Windows 10 or 11 installed,
- Active Bluetooth v2.0 port.

Although the program can start in a less powerful environment, in that case we cannot take responsibility for its fast and reliable operation.

Recommended operating system

- Windows 10 or 11

Installation

Insert the CD in your computer's CD ROM or connect the flash drive into the USB port. The installation will start automatically. If it doesn't initiate, double click on the **setup.exe** file and the installer will launch the setup.

Note:

- If you want to install the software, select the "Full installation" option!
- If you want to update to a new version of the already installed software, select the "Upgrade installation" option!

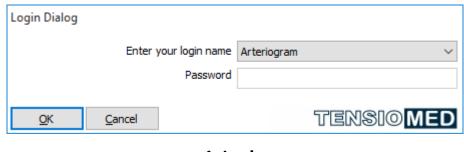
At the end of installation, the TensioWin shortcut can be created and placed on your desktop.

You can start using the program by double clicking on the *TensioWin* icon.



3.2 The structure of the TensioWin software

For proper operation please choose your own account and enter your password. When starting the software a login dialog window appears. From the drop-down list any formerly registered login name can be selected. You can also choose the default login name "Arteriogram".



1. Login

The control panel of the software consists of three main modules (see the picture below):

									TENSIO
Patient details High SBPao and SBP I	or High Aixao and wv							Results High SBPao and SBP b	r Hi
New		🚨 Edit					X Delete	Graph view	Delete
Search for						Search by Name	◯ ID number	Start test A24 2013. 11. 13. 7:45:00	Receive Date / Time 2013. 11. 15. 8:43:07
Family name	First name	ID number	J-S	Height	Weight	Arm circumference	^		
High SBPao and SBP br	High Aixao and Pwv	norm DI	52	170	74	29			
Higher SBPbr High PWV ao	Normal Aixao SBPao	6	52	164	72	30			
Higher SBPbr High SBPao	High Aixao and PWV	2369	46	153	56	25			
Increased Pulse Pressure	LVH	1		170	104	0			
ISH overdipper	High PWVao	1952	54	185	82	29			
Isolated Systolic HT	Non dipper	3		160	65	0			
Normal SBP br	Normal SBPao	879	51	160	65	28			
Normal SBPbr and SBPao	Higher Aix and PWV	5	54	168	97	34			
Normotensive non dipper	WC HT	4		162	80	0			
Normotensive overdipper	CHD ACBG	2		172	74	0			
ID number norm DI Age 57 BMI 25,61	o and SBP br High Abxao and P Heigh Weigh Arm dicumferenc JUG-S	t 170 cm t 74 kg e 29 cm					Sex male female	Start Awake O6:00 Sleep 22:00 Special 06:00 Conclusion	40
		Plan setup - Data t	ransfer				5		v
High SBPao and SBP br I								200	
	p protocol and program device					a from device		150	min

2. Control panel

1. The first module shows the details of the currently selected patient and functions for adding new patients, editing or deleting data and searching among patients.

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3. Patient data

2. In the second module communication with the operated device can be initiated, i.e. programming the device or downloading measured data from it.

Protocol High SBPao and SBP br High Aixao and Pwv	
Plans	setup - Data transfer
Set up protocol and program device	Retrieve data from device
Singl	e office measurement
	e measurement (Valid only with Arteriograph24)

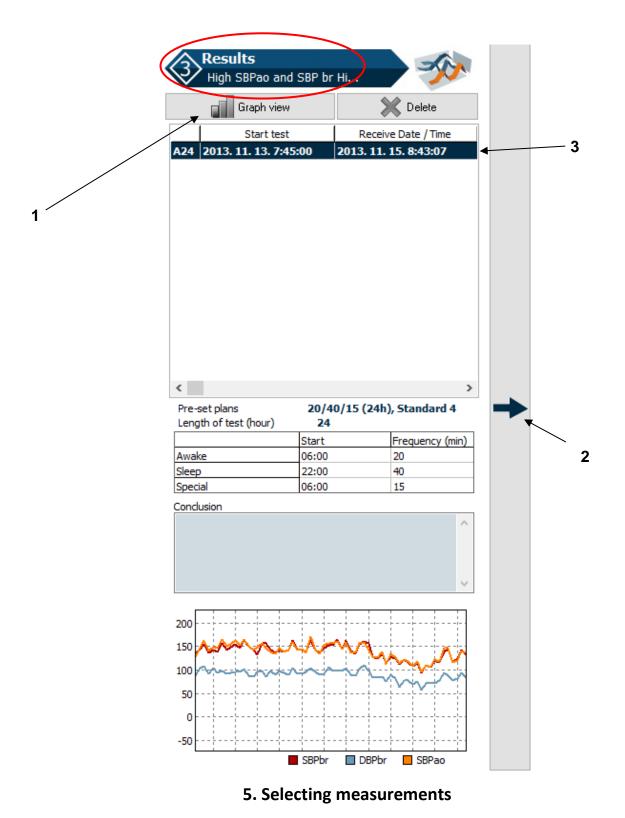
4. Measurement

3. The third module shows the list of the measurements of the currently selected patient along with the preview of the selected measurement.



Selection can be done by:

- 1. Clicking on the chosen measurement and selecting the "Graph view" button.
- 2. Clicking on a given measurement and selecting the "Continue" button signed by an arrow on the right.
- 3. Double click on the measurement.



3.3 The menu bar of TensioWin

The menu bar contains the menu items through which all major functions are available.

File

<u>Import data file:</u> Opening a TensioWin data file received from an external source, using the password generated by them.

Export data: The data of the selected patient can be exported for further analysis

Import from a database: To import a previously saved TensioWin database

Backup database: Backup database for safety purposes by selecting the path for the backup file.

Exit: Shutting down the program

View

Toolbar: display or hide toolbar

Status bar: display or hide status bar

Button labels: display or hide the labels on the Toolbar buttons

Patient details: display or hide the selected Patient's data.

<u>Patient functions</u>: display or hide the available functions of the selected Patient (new, edit, delete)

Confirm currently selected patient

Operator

You can add, edit or delete the operator's data here.

<u>Change Operator:</u> Login to a user account.

<u>New:</u> A new account can be added by clicking on this option.

Edit: The data of a selected user can be edited here.

<u>Delete</u>: Data of a selected user can be deleted here.

<u>Allocate patient:</u> The patients assigned to other operators can be allocated to the current operator.

Patient:

Add, edit or delete patient data.

<u>New:</u> A new patient can be added here.

Edit: The data of a selected patient can be modified.

Delete: The selected patient can be deleted.



Device types

Search device:

The available, already paired devices around the computer can be detected.

The required device type can be selected (It can be changed before setting up the communication). The devices are as follows:

- TensioDay 1(24-hours ABPM)
- TensioDay (24-hours ABPM)
- TensioDay Plus (24-hours ABPM + central aortic blood pressure)
- Arteriograph24 (24-hours Arteriograph)

Protocol menu

Set up protocol and program device:

This menu item allows you to prepare the blood pressure monitoring schedule and to download the plan to the TensioMed[®] device.

Retrieve data from device:

This menu item allows you to download the blood pressure data recorded by the TensioMed[®] during the monitoring period and display it.

Single office measurement:

This function works only for Arteriograph24 devices which were produced from 2016.

Tools

Windows control panel

All the major functions of windows control panel are available from here.

- Telephones and modems
- System
- Bluetooth® tools
- Time and date setup

E-mail settings

The parameters for the e-mail function of the software can be set here.

<u>Setup</u>

By clicking on this menu item you can modify the following settings of the device:

- you can set the initial pressure of the device to:
 - \circ an arbitrary value
 - \circ 50 mmHg above the previous MAP value
- examination of the cuff inflation,
- you can set the device to repeat the faulty measurements,

- - you can download the actual date and time into the device,
 - you can change the language.

These settings only take effect after sending those to the device by pressing the "Download into the device" button.

Select the type of the device.

Select the proper comm. port and the port limit until which the software will search for the device.

Activate/deactivate the following functions:

- Types of the devices are shown,
- The Arteriograph function is shown,
- View results on the screen,
- Auto JUG-SY,
- Calculation of Ankle-brachial index (ABI).

Note: The Auto JUG-SY function should not be used on patients from the Far East population (Chinese, Japanese, etc.). In this case the PWV value is not calculated properly, and only the Return Time (RT) is accurate.

Information menu

Help files: This function provides you with help in using the software.

<u>User's manual</u>: The User's Manual can be accessed. To use this function a program capable of reading PDF files should be installed to the PC.

Manufacturer and software version information



4. Using the TensioWin software

4.1 Operator's data

Add new operator/physician

If you want to add a new user, go to tab "Operator/New" and enter the data of the new user in the pop-up window. Note that the colored fields are mandatory to be filled out. Click OK to save the data. The name of the new user will be listed in the login names list upon starting the software.

Selection of the operator

If you intend to choose a different operator than the one which is already logged in, select "Change Operator" from the drop-down list of "Operator" in the main menu bar. Find the user in the list and select it by clicking on the name and then clicking the "OK" button. The name of the selected user is indicated in the header of the window.

Edit operator data

If you want to modify or edit previously entered user data, go to the tab "Operator/Edit". Modifications can be saved by clicking "OK".

Delete operator

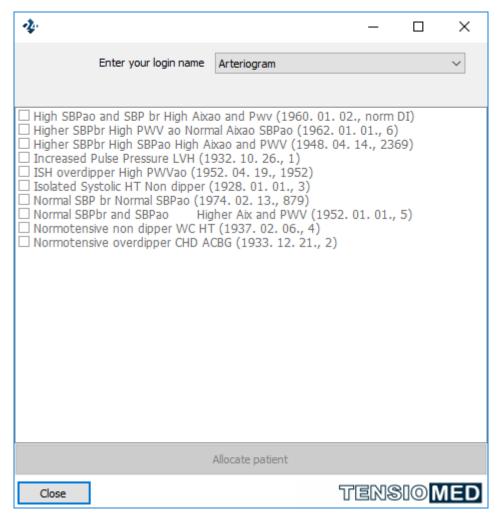
You can delete one or more operators at a time via the "Delete" menu item. Simply select that operator and press "Delete" button. The action will only be performed if the correct password of the particular operator was given. To complete the operation, TensioWin software has to be restarted.



6. Delete operator

Allocate Patient

If you would like to duplicate the data of a patient who is already assigned to another operator, use this function. From the pop-up window you can select to allocate the patients only if you are aware of the assigned operator's password. To complete the allocation, select the proper patients and press "Allocate patient" button.



7. Allocate patient

4.2 Patient's data

Selection of the patient

You can select any patient in the "Patient details" module of the main window by clicking on them or with the "Search for" function. You can search for names or ID numbers by toggling the setting on the right side of the search bar.

Add a new patient

If you want to add a new patient, click "New" in the "Patient details" module or go to the "Patient - New" menu item. A pop-up window appears where the patient details can be entered. The structure of this form corresponds to the steps of a usual outpatient visit. Entering information on medical history, current complaints, examinations, laboratory data and assessing cardiovascular risk is possible, but not required. You can save data by



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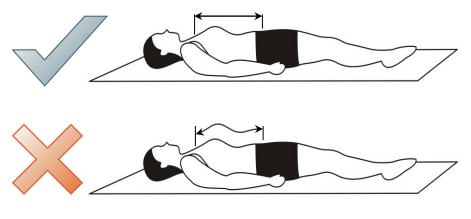
clicking "OK". Comments or opinions given here are automatically added to the printed report. Please, note that the following highlighted fields must be filled:

- ID number
- Family number
- First name

In case of TensioDay PlusTM and Arteriograph24TM devices the following data must be entered:

- JUG-SY (Jugulum-Symphisis distance). If the Auto JUG-SY function described on Page 13 is activated, this value is automatically calculated from the provided height.
- Arm circumference
- Height

After adding the arm circumference, the software automatically suggests the proper size of cuff to be used. The suprasternal notch (jugulum) – pubic bone (symphisis) distance should be measured in a straight line. Measuring on the body surface can lead to overestimation (e.g. in case of obese patients).



8. JUG-SY measurement

Measure the suprasternal notch – pubic bone distance (Jug-Sy). A tape measure is supplied.

Edit patient data

If the patient returns to the clinic for a follow-up visit or has new laboratory or blood pressure data, you can edit the patient data and prepare a follow-up report. To do so, select the patient in the "Patient details" module whose data you want to edit and click the "Edit" button or go to the "Patient/Edit" menu. A pop-up window appears where the patient details can be modified. In the "Baseline symptoms", "Physical examination", "Office blood pressure" fields the current date will automatically be displayed. You can review previous data by using the scroll bar. Only data entered with the latest date will be printed in the report. Modified data can be saved by clicking on the "OK" button.

Enter and delete office blood pressure data

If you want to enter new office measurements to a particular patient's data, select the desired patient, then click "Edit" on the Patient details window. Click on "Next".

Patient details				×
Demographics				
ID number	2369			
Family name	Higher SBPbr High S	BPao		
First name	High Aixao and PWV	/		
Date of Birth	14.04.1948.		BMI 2	3,92
Height	153 cm	Arm circumferen	ce 25	cm
		Weig	ht 56	kg
Suggested cuff	type M (55x14cm))		
Referring doctor	Dr. Illyés Miklós			
Postal code				
Region				
City				
Address				
Telephone				
Fax				
Mobile phone				
E-mail				
Comment				
Sex				
 male female 				-
• Ternale				
				-
	Next >>			-
OK Cancel		TED	NSIO M	IED

9. Entering office blood pressure data

Enter the systolic and the diastolic blood pressure reading, and the heart rate value, then click "Save".

Entered values will be listed in the right panel with the date and time. Repeat these steps for each office reading. The average of the readings from the same date is automatically calculated and displayed on the bottom of the panel and can be printed as well.

If you want to delete previously entered office blood pressure data, first select the row you want to delete by clicking on it. These data will now appear on the left side of the Office BP panel. Delete these data by clicking "Delete".

Enter cardiovascular risk factors

The software allows you to enter clinical data that determine cardiovascular risk and to calculate this risk. Open the "Patient details" window of the patient to whom you want to enter cardiovascular risk factors and click on the "Risk factors" button. This brings you to the Cardiovascular risk factors window, where you can enter the data. Click "Save new data" to save the data.

Enter and delete laboratory data

You can enter laboratory data of the patient in the Cardiovascular risk factors window. At the top right of the window, you will find prepared fields for entering some of the laboratory values. If you want to enter new data select the "New lab data" button in the

laboratory data panel. Fill in the fields and save the data by clicking on the "Save" button. You can select the unit of measure of the values to be entered (e.g. mmol/l or mg/dl). After saving the provided data the current date will be added to the panel. You can review previously entered laboratory values by clicking on the "Previous lab data" button.

If you wish to delete a set of laboratory data, simply find the data by using the Previousor Next lab data buttons and then click "Delete". All laboratory data belonging to that date will be deleted.

Print cardiovascular risk factors and laboratory data

Select the "Print" button on the cardiovascular risk factors window. A print preview of the page will be presented with the risk factors, laboratory data, and the estimated risk of cardiovascular disease in the next 10 years for the patient. The risk is calculated according to the equation derived from the Framingham study (Anderson KM. et. al. Cardiovascular disease risk profiles. Am Heart J 1990;121:293-8). The data needed to calculate the risk level are date of birth, sex, systolic blood pressure, current smoking status, diabetes, left ventricular hypertrophy detected by ECG, cholesterol and HDL-cholesterol values.

5. Programming the device

To set up a measurement protocol and to program the device, press the "Set up protocol and Program device" button on the "Protocol" module, "Plan setup – Data transfer" section.



10. Programming

In the "Set up protocol and Program device" window you can either select a pre-set monitoring plan for the ambulatory monitoring or create your own protocol.

The monitoring protocols are characterized by:

- the length of the test (measurement) in total: 24,36,48,60 or 72 hours
- the active (Awake), the passive (Sleep), and (optionally) the special periods. The latter may be needed if there is a period of special interest (e.g. early morning hours before awakening) during which a different measurement frequency may be needed.
- the starting time, length and number of the test
- the starting times and measurement frequencies during the active, passive (and, if included, special) periods

✤ ABPM protocol setup			×
Tools View			^
Tools View			
		$\langle 2 \rangle$	
Patient High SBPao and SBP br Hig	jh Aixao and Pwv	Please select the type of dev	/ice!
Pre-set plans		Device type	
15/30 (24h) Standard 1 30/60 (24h) Standard 2 30/60/15 (24h) Standard 3		⊖ TensioDay TD1	○ TensioDay Plus
20/40/15 (24h) Standard 4		○ TensioDay	Arteriograph24
New	Delete		
Start test	09.05.2017 10:39	×	
Length of test (hour)	24 ~	Offset of systolic pressure le	evel
Test number	Test 2	-120 mmHg <= 40	<= 120 mmHg
Awake		Communication ports	
Start	06:00	COM5 Arteriograph24 (11/1	TD3A0048) - 🗸
Frequency (min)	15 ~		
Sleep			
Start	22:00		
Frequency (min)	30 ~		
Special			
Start			
End			
Frequency (min)	~		<u>S</u> end
Close			TENSIO MED

11. Measurement protocol

Pre-set plans are listed in the window. The first number in the name of the pre-set plan refers to the measurement frequency during the active period; the second number denotes the measurement frequency during the passive period; and the third number indicates the measurement frequency during the special period (i.e. 30/60/15). The length of the planned monitoring is indicated by the number in parenthesis (24h). Even when selecting a pre-set plan, you can modify the length of the test, the start time of the test, the different periods, and the measurement frequencies of the different periods. Measurements can be programmed up to 72 hours with frequencies from 10 to 90 minutes.

If you want to use monitoring schedules different from those listed in the pre-set plan window frequently, select "New". This allows you to define new, customized protocols that can be programmed quickly later. When preparing a new pre-set plan you can define the length of the test and the measurement frequencies for the "active" daytime, "the "passive" night-time, and for an additional "special" period. Save the new pre-set plan by clicking OK after naming the new pre-set plan. The details of the new pre-set plan appear in the window.



New pre-set plan	×	

New pre-set pla	n		×
Awake	Frequency	(min)	~
Sleep	Frequency	(min)	~
Special	Frequency	(min)	~
	Length of test	(hour)	~
	Plan name		
<u>О</u> К	<u>C</u> ancel	TE	NSIO MED

12. Protocol setup

You can always modify the starting time of the test.

Once the protocol is set, click on the "Send" button.

As several TensioMed[®] products can be managed by the TensioWin software, the proper type of device has to be selected when initializing data transmission.

If the communication port is not known, the selection of the required port (device) is possible from the drop-down list. The software has an automatic port selection feature which detects the currently connected active device and initiates its connection with the PC.

Warning! Make sure that the clock is displayed on the screen before communication starts; neither "BLUELINK" or "CONNECT" should be seen.

Click "Send".

If there are more devices available, but only one is intended to be used – of which the communication port is known – TensioWin is capable of connecting only via the selected communication port. This way the automatic search can be avoided and it is impossible to re-program another device connected to a different port.

The process of download of the measurement protocol to the device can be followed on the progress bar. "CONNECT" is displayed on the screen of the device. The successful download is confirmed.

In case you wish to delete the previously registered devices from your list, choose "Tools" from the menu of the "Set up protocol and program device" window and select "delete the previously registered devices".

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5.1. Single office measurement

From the TensioWin program it is possible to start a single Arteriograph measurement without first programming the device.

This function is only available for Arteriograph24 devices produced after 2017. To start the single office measurement, push the "Single office measurement" button at the bottom of the display:



13. Single office measurement

A communication port selection window will be displayed after the patient data retrieval has been approved.

The measurement can be started with the "Start" button.

During the measurement process, a communication window is displayed while the Arteriograph24 performs the measurement and forwards the data to the TensioWin program. After the results become available, they are displayed on the report.

For evaluation and management of the findings, see the chapter on analyzing and evaluating data. (Chapter 7.)

6. Retrieve data from the device

If you want to transfer data from the Arteriograph24 or TensioDay Plus device to the computer, select the proper patient from the list and click the "Retrieve data from device" button in the "Plan setup – Data transfer" section.



14. Retrieve data

The pop-up window for the device and port selection appears:



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se select the type of dev	vicel	
Device type	vice:	
) TensioDay 1	○ TensioDay Plus	
○ TensioDay	Arteriograph24	
2 Communication ports		
Communication ports COM5 Arteriograph24 (1	11/TD3A0048) ~ 🔎	
COM5 Arteriograph24 (1	(1/TD 3A0048)	

15. Selecting the device and the communication port

As several TensioMed[®] products can be managed by the TensioWin software, the proper device type & connection port have to be selected when initializing the data transmission.

Select the "Download measurements of current patient to the PC" option from the dropdown list of the "Tools" menu on this window.

Note: if the device was not programmed with the same computer as the currently used TensioWin software is installed on, a notification will appear. Ensure that you use only one computer with the device to avoid mismatching information. Also, confirm during the retrieval of the data to select that patient from the list of whom the measurement was taken.

You can transfer the blood pressure data any time during a particular ambulatory blood pressure monitoring examination. This may be necessary, for example, if you want to check the performance of the device or see the blood pressure values while the measurement is in progress. The data transfer does not affect the set protocol, and after data transfer the examination will resume until the set length of the protocol is completed. If you transfer data while the examination is in progress, i.e. before the measurement is complete, this fact is shown in the "Status" window of the first page of the "Analysis". If you transfer additional data from the same examination (e.g. at the end of the monitoring) these new data will be appended to the partial results transferred previously to allow complete data analysis.

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7. Analysing data, evaluating measurements

In the "Results" module of the main page select the desired examination from the list of the given patient.

The three pages of analysis are now available:

- "Study data"
- The graphical page of "Results"
- Page of "Statistics"



16. Graph window

The **Analysis page** can be personalized. Selecting "View" from the main menu certain parts of the window can be hidden/displayed.

The below functions are available via **Tools** in the main menu:

1. Export

The complete measurement results can be exported in a .txt (text file) or .xls (Excel file) format.

2. Save

The measurement can be saved as a special data format to be portable and readable in another TensioWin. If there is no password defined, the saving and later the importing can be performed simply by clicking on the "OK" button.

3. Save PDF Report

The report of the selected measurement can be saved in PDF format.



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4. Save and send

This is a complement to the previous "Save" function with a further option for sending emails including the saved measurement together with the "standard report".

5. Preview

The preview is an indication of what the printed report document will look like. The content of the displayed data can be selected after clicking on the "Setup" button. Please refer to section 8. "Print a report".

6. Print Standard report

The printing of the measurement results in the form of a "Standard report" can be initiated from this window.

7. Return to the main device menu screen

The Results window is closed using this option.

7.1. The Study data

This section contains the patient and operator identification data and the status of the measurement (in progress/completed), along with the measurement protocol data and the device type. Two control panels can be opened from this window:

- Day/Night set
- ABP Thresholds

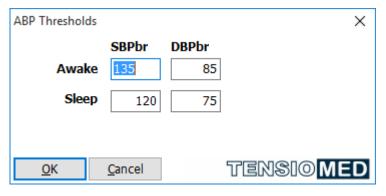
During analysis, the active and passive periods can be modified. This function is relevant if the patient did not follow the prescribed "Sleep" and "Awake" periods. Selecting the "Day/Night set" buttons you will see as follows:

Day/Night set	×
Awake start	Sleep start
	1. 13.11.2013 21:30
2. 14.11.2013 06:30	2. 14.11.2013 22:00
3. 15.11.2013 06:00	3. 15.11.2013 22:00
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17. Setting Day/Night

If you change the start- and endpoints of the active and/or passive periods, then the graphical review of the analysed data will be based on the modified time setting.

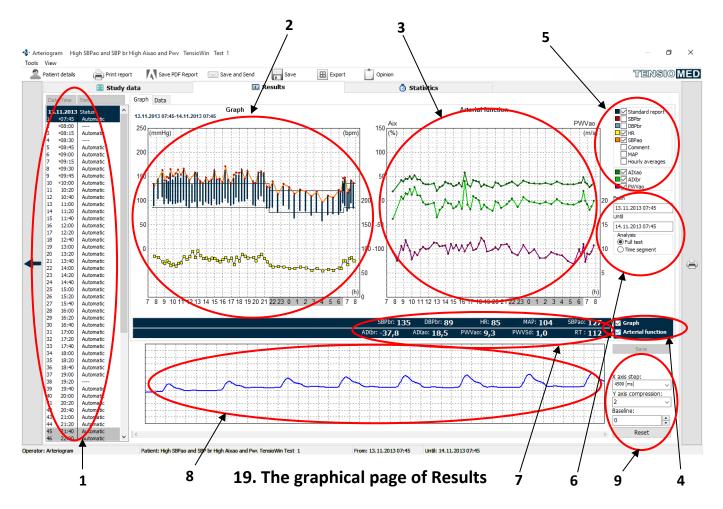
The blood pressure limit values can also be changed here selecting the "ABPM thresholds" button.

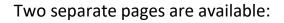


18. Setting the thresholds

TensioWin software will display this threshold with a black line on the blood pressure curve.

7.2 The Results window





The Graph page

The signs of Figure 19. are as follows:

- 1. Standard measurement list
- 2. Blood pressure histogram
- 3. Arterial function histogram
- 4. Blood pressure histogram/Arterial function histogram display/hide
- 5. Select the displayed parameters
- 6. Select the displayed period
- 7. Numerical parameter values
- 8. Pulse wave curve
- 9. Display settings

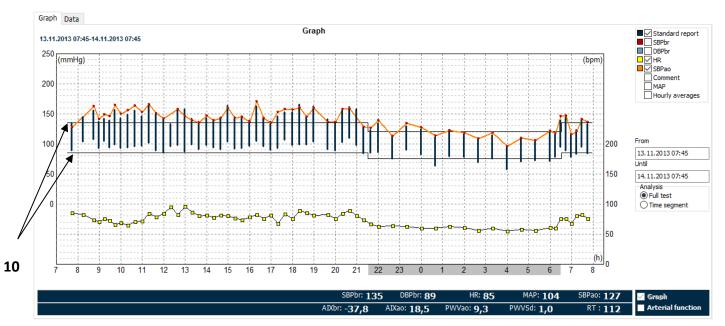
For TensioDay and TensioDay Plus devices, the sections 3. 4. and 8. are not available.

Standard measurement list (1)

The measurement list facilitates a better connection between the measurements of a given patient. Upon selecting a measurement, red lines will show the corresponding sections on the Arterial function histogram (3)* and the Blood pressure histogram (2), respectively. The parameter values belonging to the measurement will be displayed on the Numerical parameter values section (7) and the related pulse wave curve section will appear on the Pulse wave curve (8) display.

*In case of Arteriograph24

Blood pressure histogram (2)



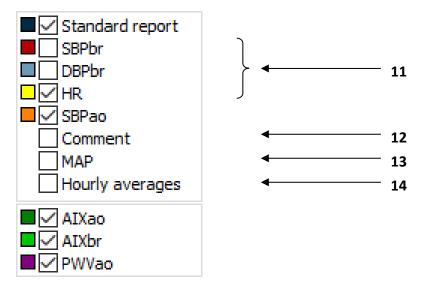


The graphical display of the measurement data can be seen here. The set threshold values for the systolic and diastolic blood pressures for the active and passive periods are indicated by solid black lines (10).

Note: you can modify at the "Study data" page both the threshold values as well as the start and endpoints of the active and passive periods.

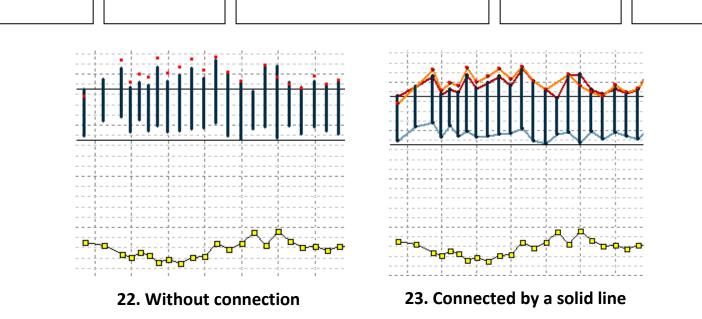
The pill intake is indicated by a green dot on the top of the graph. There are several options for customizing the graphic display:

- the data on the histogram may be displayed as discrete values or as a continuous curve (Figure 19-20) (11)
- the comments typed in on the 2nd page can be displayed (12)
- toggle the display of the mean arterial pressure (13)
- you can view either the individual measurements or the hourly averages (14)
- either the full test period or only a time segment of it may be viewed. Clicking on "Time segment" at the bottom of the page allows defining the time segment to be displayed (6)



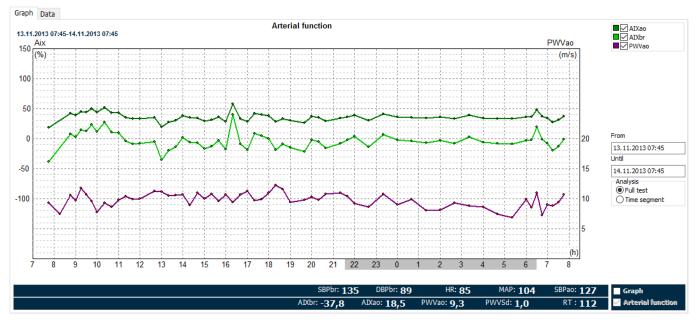
21. Editing the graphical display





Arterial function histogram (3)

The graphical display of the arterial function parameters is depicted on this graph. Similarly to the Blood pressure histogram the active and passive periods can be modified at the "Study data" page.



24. Arterial function histogram

The Aix_{ao} (aortic augmentation index), Aix_{br} (brachial augmentation index) and PWV_{ao} (aortic pulse wave velocity) parameters can be displayed or hidden.

Thus, it is possible to evaluate the arterial function parameters and the additional data measured by Arteriograph24 either conjoined or separately. It can easily be done by clicking on the checkboxes above the graph: "Graph" and/or "Arterial function".

 			 - P	

Pulse wave curve

The Arteriograph24 device records the pulse wave curves for each measurement. If you coordinate via the Standard measurement list (1), the required Pulse wave curve can easily be selected. By default, the software analyses the curve, but manual evaluation is also a possibility. To do so, click to the starting point of the required section of the curve and keep the mouse button down while selecting the required section. To complete the selection, simply release the button. TensioWin software automatically tries to evaluate the given section, the numerical results of which will appear on the screen above (7) in case of success. If this latest result is preferred to be stored instead of the standard evaluation, select the "Save" button.

The Data window

The Data window is the tabulated list of the time, the date and the measurement data. The passive period is indicated by the shaded area and the special period by an "*" at the beginning of the row. The status column indicates whether the reading is the result of an automated or a manual measurement. The status column also lists the time of pill intakes and the time of waking up or going to bed. The comment column can be used to type in comments to a particular reading (e.g. dizziness noted by the patient) by double-clicking on the Comment section on the correct row.

While the blood pressure and arterial stiffness measuring algorithms of the device automatically discards extreme blood pressure and heart rate values, the summary statistics is based on all data listed in this page. You can manually deactivate a particular reading by double clicking on that row. Selecting the checkbox, the given parameters of the measurement will be inactive – as temporarily being deleted. In the case of Arteriograph24, there's a possibility to deactivate only the parameters of arterial function ("Delete Arterial Function parameters of the measurement").



13.	.11.2013					HR	SBPao	AIXao	AIXbr	PPao	PWVao	PWVSd	RT	Comment
1	*07:45	135	89	104	46	85	127	18,5	-37,8	38	9,3	1,0	112	
2	*08:00													False measurement (A)
3	*08:15	145	104	118	41	82					7,4	2,4	141	
1	*08:30													False measurement (A)
5	*08:45			124	48	74	163	41,7	8,1	55	10,6	0,3	98	
5	*09:00		93	108	44	71	141	39,0	2,7	48	9,7	0,7	107	
7	*09:15			117	37	75	149	45,1	14,7	44	11,7	0,3	89	
3	*09:30		94	109	45	73	146	44,2	12,9	52	10,7	1,2	97	
9	*09:45		99	118	58	66	165	49,6	23,7	66	9,6	0,9	108	
10	*10:00		93	110	50	69	150	43,7	12,0	57	7,7	1,6	135	
11	10:20		94	112	55	65	156	51,6	27,5	62	9,3	1,1	112	
12	10:40	156	96	116	60	71	164	43,1	10,9	68	8,7	1,5	120	
13	11:00	146	97	113	49	72	153	42,7	10,1	56	9,8	0,2	106	
14	11:20	164	102	123	62	84	166	35,7	-3,8	64	10,4	0,8	100	
15	11:40	151	89	110	62	78	151	33,1	-8,9	62	9,9	0,4	105	
16	12:00	142	86	105	56	84	142	33,4	-8,3	56	10,0	0,7	104	
17	12:20	133	96	108	37	95								
18	12:40	157	98	118	59	82	158	35,0	-5,3	60	11,3	0,3	92	
۱9	13:00	158	87	111	71	96	146	19,9	-35,0	59	11,2	2,3	93	
20	13:20	142	99	113	43	86	139	27,8	-19,4	40	10,5	2,7	99	
21	13:40	137	91	106	46	80	135	30,6	-13,9	44	10,6	0,6	98	
22	14:00	143	98	113	45	81	147	38,6	1,8	49	10,7	0,3	97	
23	14:20	138	94	109	44	77	139	34,8	-5,5	45	8,9	0,2	117	
24	14:40	142	91	108	51	81	143	34,3	-6,5	52	10,9		95	
25	15:00	164	104	124	60	80	160	29,1	-16,9	56	10,0	0,6	104	
26	15:20	145	92	110	53	76	143	31,3	-12,6	51	10,8	0,9	96	
27	15:40	143	93	110	50	74	145	36,2	-2,9	52	9,6	1,0	108	

25. Data window

After deactivating the arterial function parameters, the brachial blood pressure values will appear on the blood pressure histogram, but the arterial function parameters will not.

The temporarily deactivated parameters will neither be displayed on the graphs, nor in the statistical analysis.

Double clicking again on the previously edited reading results will mean the re-inclusion of that reading in the graph and statistics.

Measurement 14	×
Time	13.11.2013 11:20
Comment:	
	Its of the measurement nction parameters of the measurement
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26. Editing results

7.3 Statistics window

The statistics window contains 3 tabs:

The Statistics tab provides the summary statistics of the test. You can define which period to be analysed (active, passive, special), and whether the full test or only a segment of it is to be considered. The start and end point of the different periods can always be redefined. Temporarily deactivated values of "Study data" page are not included in the statistics.

The statistical summary includes:

- Mean
- Maximum and minimum
- Standard deviation
- Diurnal index (DI) that denotes the difference in mean blood pressure between the active and passive period, expressed as a percent of the mean pressure during the active period. If you redefine the start and end time of the active and passive period, the value of DI changes accordingly.
- Percent time elevation (PTE) denotes the length of time during the test the patient's blood pressure was above the threshold limits, expressed as percent of the length of the full test. The calculation assumes that the change in blood pressure between two readings is linear. If you redefine the threshold values, the PTE changes accordingly.
- Blood pressure load (Load) denotes that area under the blood pressure curve where the blood pressure values exceed the threshold limit.

The Correlation tab allows viewing the histogram of the monitoring data. Similar to the previous pages, you can define which period to be analysed, and whether the full test or only a time segment is to be considered. You can select the systolic, diastolic, mean arterial pressure, or the heart rate data to be displayed. The displayed histograms can be added to and removed from the print list. The "AASI" parameter displayed here is the ambulatory arterial stiffness index, which is the regression slope of the diastole upon the systole subtracted from 1.

The Histogram displays the percentages of the values falling between the particular value ranges of the following parameters:

- Systolic blood pressure,
- Diastolic blood pressure,
- Mean arterial pressure (MAP),
- Heart rate (HR).

The following display options are available:

- all data,
- the active period,
- the passive period,
- the special period (only if there was one defined).





To select the data and the period to be printed, click on the appropriate period in the "Period" list according to section 8.

You can view the plot for either the full test period or only for a time segment of the test if you switch to the Results window and set the Time segment at the "Analysis" section.

7.4. Opinion

An opinion of the current measurement can easily be added by clicking on the "Opinion" icon at the toolbar. The pop-up window of "Opinion" is divided into two parts. The upper part contains the previously added comments, while the section below is the editable field of the new opinion. This window is also portable, while swapping the pages of the measurement. This way the curves, parameters or statistics can easily be checked while adding a comment.

8. Print a report

There are several options for printing the results:

By clicking on the "print" icon to the right of the Analysis window or the "Preview" button at Tools menu, you can compile and print out the desired report type.

There are 5 report types in TensioWin:

- Report
- Cardiovascular risk factors
- Standard report
- Arterial function
- Data

Print		×
Standard report		
Report Cardiovascular risk factors Standard report Arterial function Data		
	Setup	
Preview Cancel		TENSIO MED

27. The Print window

These types can be printed individually or combined. The selection is performed by checkboxes in the Report window after clicking on the Setup button in the Print report

window. There are also report elements which can be added/removed to/from the report in this window.

Standard report

The generally used report form can be set here.

The default setting is as follows:

Standard report of 2 pages:

- a summary report together with the blood pressure histogram and the corresponding statistics
- corresponding opinion

In the case of Arteriograph24, the standard report above can be completed with the "arterial function" report by selecting the arterial function report type in the Setup.

Report	×
 ☐ Report ☐ Cardiovascular risk factors ☑ Standard report ☐ Arterial function ☑ Data 	Correlation All data Awake Asleep Special
Histogram All data+Systolic All data+Diastolic All data+MAP All data+HR	Awake+Systolic Awake+Diastolic Awake+MAP Awake+HR
Asleep+Systolic Asleep+Diastolic Asleep+MAP Asleep+HR	 □ Special+Systolic □ Special+Diastolic □ Special+MAP □ Special+HR
Graph IIII Comment MAP Hourly averages Comment+MAP MAP+Hourly averages Comment+Hourly averages Comment+MAP+Hourly averages	Comment MAP Hourly averages Comment+MAP MAP+Hourly averages Comment+Hourly averages Comment+Hourly averages
Save	TENSIOMED

28. The settings of the desired report

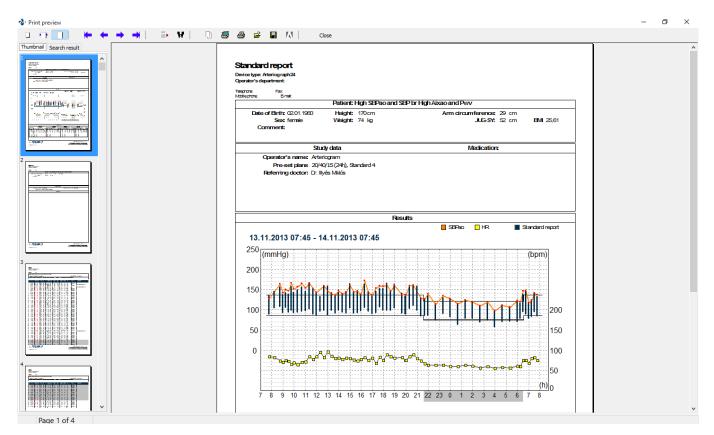
	1	
	1	
		-

After you set the desired report for printing, click on "Preview". Now the "print setup" window appears:

Print			×
Printer			
Name:	Microsoft Print to PDF	 ✓ Properties 	s
Status: Type: Where: Comment:	Ready Microsoft Print To PDF PORTPROMPT:		
Print range All Pages Selection	from: 0 to: 0	Copies Number of copies: 1	Collate
		ОК Са	ancel

29. The Print setup window

The required printer can be selected and configured here. If it is done, select "OK", then the print preview appears.



30. Print preview

With the use of the toolbar on this screen the following functions can be accessed:

Zoom tool

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The print preview page can be zoomed to fit the screen height (Zoom to fit),

to fit the screen width (Zoom to width), to the original size (100%), or a percentage value between 50% and 200%.

Navigation tool

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This tool can be used to navigate to the First page, Previous page, Next page or to the Last page of the medical report.

Search tool

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Using these tools, a search can be performed by page number (Go to page) or by a keyword (Search for text).

Copy tool

The current page of the report can be copied to the clipboard with this tool.

Print tool

A printer can be selected and set up using the first icon. We recommend Microsoft Print to PDF, as certain pdf writer software may not depict the graphs on the measurement report. The page can be printed with the previously determined settings by clicking on the second icon.

Load tool

The patient's previously saved reports can be selected and displayed by clicking on Load Report in the Print preview dialog box.

Close

Close The Print preview screen can be closed by using this button.

9. Import a database

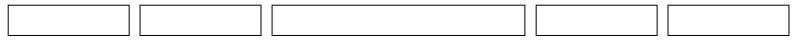
TensioWin software is capable of importing the database of a former TensioWin program version so the previous data will be operable via the new software.

Import	×
Type of the Database	
TensioWin 1.	◯ TensioWin 2.
Paradox	MsAccess
Browse a Paradox Database	Browse a MsAcces Database
Source:	Source:
Start import	Start import
1	
OK <u>C</u> ancel	TENSIO MED

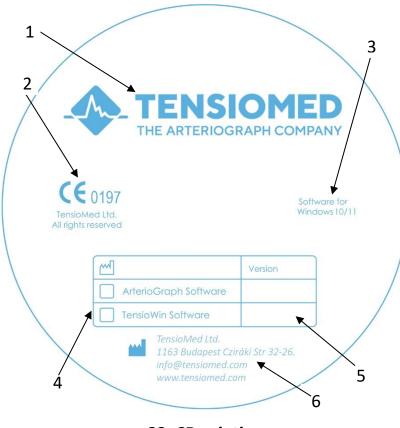
31. Import a database

The process of importing a database is as follows:

- You can import a database from the File menu.
- Select the version of the software you intend to import from (TensioWin 1. or TensioWin 2.)
- The selected part of the window is always active. i.e. if you intend to import from TensioWin 1. select "TensioWin1" button and click on "Browse a Paradox Database" giving the direction of the database. (The default is: "C:\Program Files\TensioMed Ltd\TensioWin\Data"). To launch the process, click on the "start import" button.
- After finishing the import and noting the warning message, restart the TensioWin program.



10. Install CD design



32. CD printing

Information on the install CD

- 1. The name of the manufacturer of the devices that TensioWin software is used with.
- 2. The number of the Notified Body which certified the devices that TensioWin software is used with.
- 3. The operating systems which the software can properly operate on.
- 4. The name of the user software (TensioWin software in this case).
- 5. Version number (defined based on the current software release).
- 6. Data related to the manufacturer.

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11. Troubleshooting

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Problem	Device type	Possible causes
No communication	TensioDay TensioDay Plus Arteriograph24	 Communication adapter is not connected, the device is not recognized by the PC, no batteries or low batteries in the device, or the device was turned off
No SBPao values are displayed	TensioDay Plus Arteriograph24	Loose cuff,arrhythmia,
No arterial function parameters are displayed	Arteriograph24	or tremoroutdated memory module
No print preview	TensioDay TensioDay Plus Arteriograph24	No printer has been installed on the PC.
The PDF report cannot be opened	TensioDay TensioDay Plus Arteriograph24	Adobe Reader is not installed on the PC.
Database import cannot be completed	TensioDay TensioDay Plus Arteriograph24	Not the proper database was opened, or the database was damaged.