TENSIOMED®

TENSIOWin™

For Microsoft Windows 7/8/10

User's Manual

Please read the user's manual carefully before the first use!

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

PC software

TensioMed® TensioWin-03v7-00

Revised: 01-07-2021

Table of Contents

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 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 relevant device's intended use which the TensioWin software operates. The TensioWin™ software is a Standalone software, but the above-mentioned devices are essential for its medical operation.

TensioWin™ software is explicitly designed for professional (clinical) use and not for home use. *TensioWin software is designed for multiple 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 intended use of the TensioWin™ software is to manage the TensioDay, TensioDay Plus and Arteriograph24 instruments. The function of the TensioWin™ software is to send the measuring plan, required for the operation of the above-mentioned instruments, from the doctor's computer to the devices, furthermore to read out the measured data from the devices into the physician's computer, where the TensioWin software structures the measured data. **Before use, please read carefully not only the TensioWin User's Manual, but the User's Manual of the relevant device, which the TensioWin software operates.** You can also find contraindications to the use of the instrument and precautions for use here.

The intended use of the operated devices:

Arteriograph24 medical device: The TensioMed® Arteriograph24™ device measures the brachial blood pressure, the heart rate, and the arterial function parameters intermittently throughout one or more days.
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 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 Arteriograph24 is a **multiple use device**. The Arteriograph24 device 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 medical device: The TensioMed® TensioDay™ device measures the brachial blood pressure and the heart rate intermittently throughout one or more days.
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.
The TensioDay is a **multiple use device**. The TensioDay device 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 medical device: The TensioMed® TensioDay Plus™ device measures the brachial blood pressure, the heart rate, and the central systolic blood pressure intermittently throughout one or more days.
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**. The TensioDay Plus device 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® or infrared wireless data transfer between the devices and the PC.

Every effort has been made to ensure that the information in this manual is accurate. Succeeding models and manuals are subject to change without notice.

TensioMed® 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 TensioMed® TensioWin™ software.

Attention! Before first use, please read and understand this document carefully.

3. The TensioWin™software

Preliminary information about TensioWin™ software

The TensioWin™ Software is a Windows-based software. The common Windows mouse operations are to be used in the program (left single-click, double click, drag, etc.).

TensioWin™ software has two main components:

- the patient and physician database. This database is similar in all TensioMed® products, and allows for efficient patient management at a hypertension or cardiovascular clinic, for the calculation of cardiovascular risk, and for printing reports.

- the second component is specific for TensioDay, TensioDay Plus and Arteriograph24 and allows the programming of the device, the download and analysis of the measured data.

Useful addresses and telephone numbers

The Manufacturer of TensioWin™ software is:

TensioMed Ltd.
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Budapest H-1181
Hungary
Phone: +36 70 886 7337
+36 20 942 6049
Web: www.tensiomed.com
E-mail: info@tensiomed.com

3.1 Installation and setup of the TensioWin™ software

Minimum System Requirements

- A computer with processor Pentium IV, 256 MB of storage, 2 GB of free space on HDD, display of resolution 1024*768 pixels,
- Windows operational system (Win 7, Win 8, Win 8.1 and Win 10)
- Active Bluetooth® or infra port.

Installation

Insert the CD in your computer's CD ROM or connect the Pen Drive into the USB port. The installation will start automatically. In case it does not happen, double click on the **setup.exe** file on the disc and the installation setup will begin. The installation process will offer you the default directory for the program. Wait until the files are copied to the directory. At the end of installation, the TensioWin™ icon will be created and placed on your desktop.

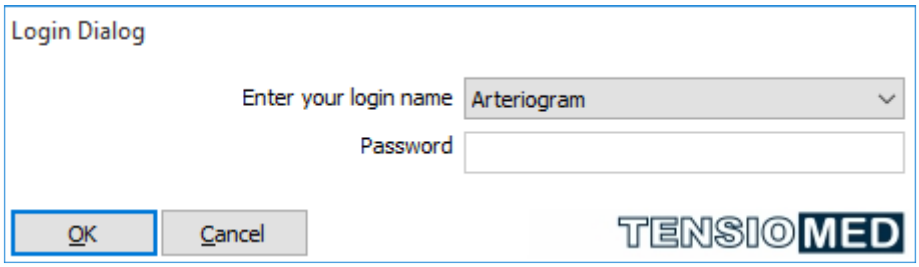
1. Installation CD for TensioWin™

Start TensioWin™

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

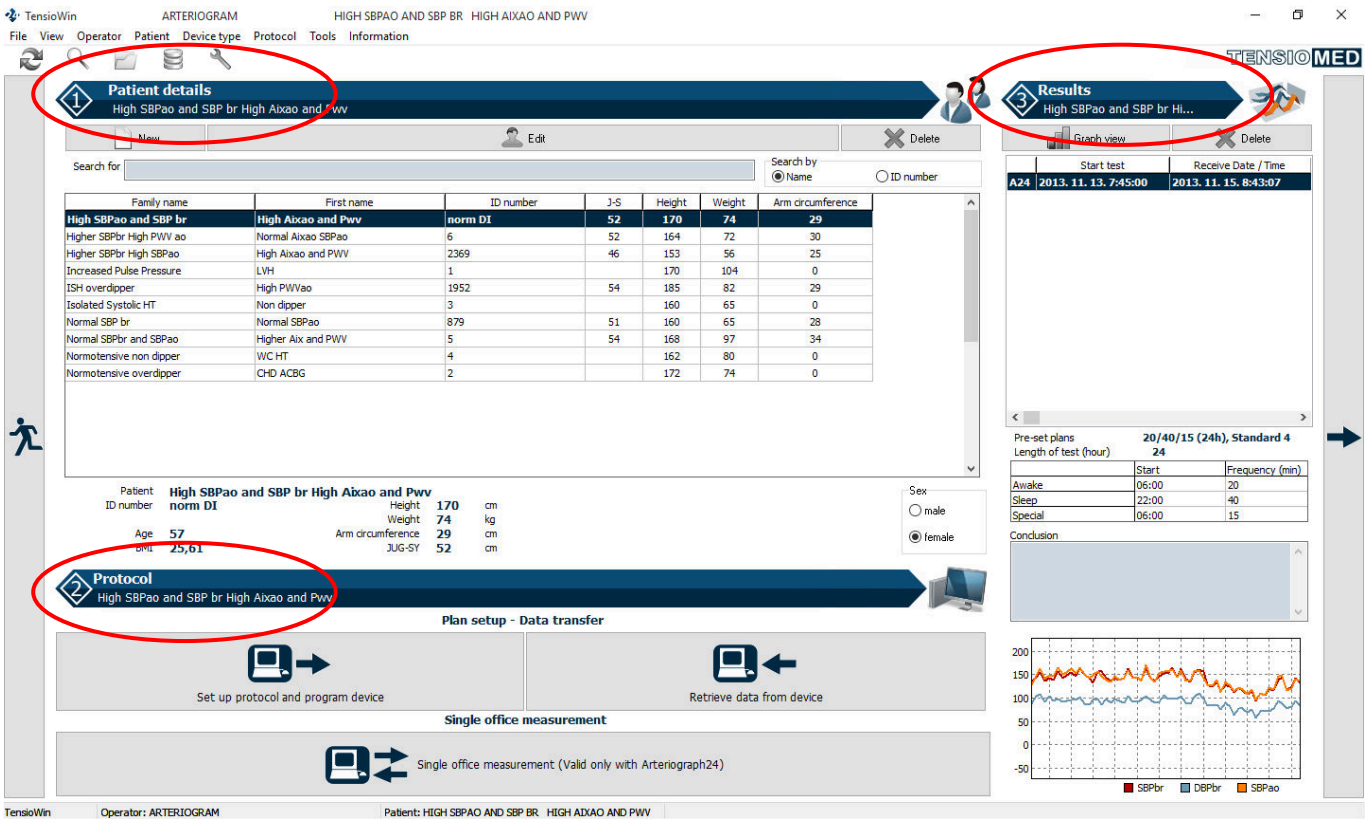
3.2 The Structure of the TensioWin™ software

For proper operation please choose the required operator and enter the proper password. When starting the software a login dialog window appears. From the drop-down list any formerly registered login name can be chosen. You can also choose the default login name “Arteriogram”.



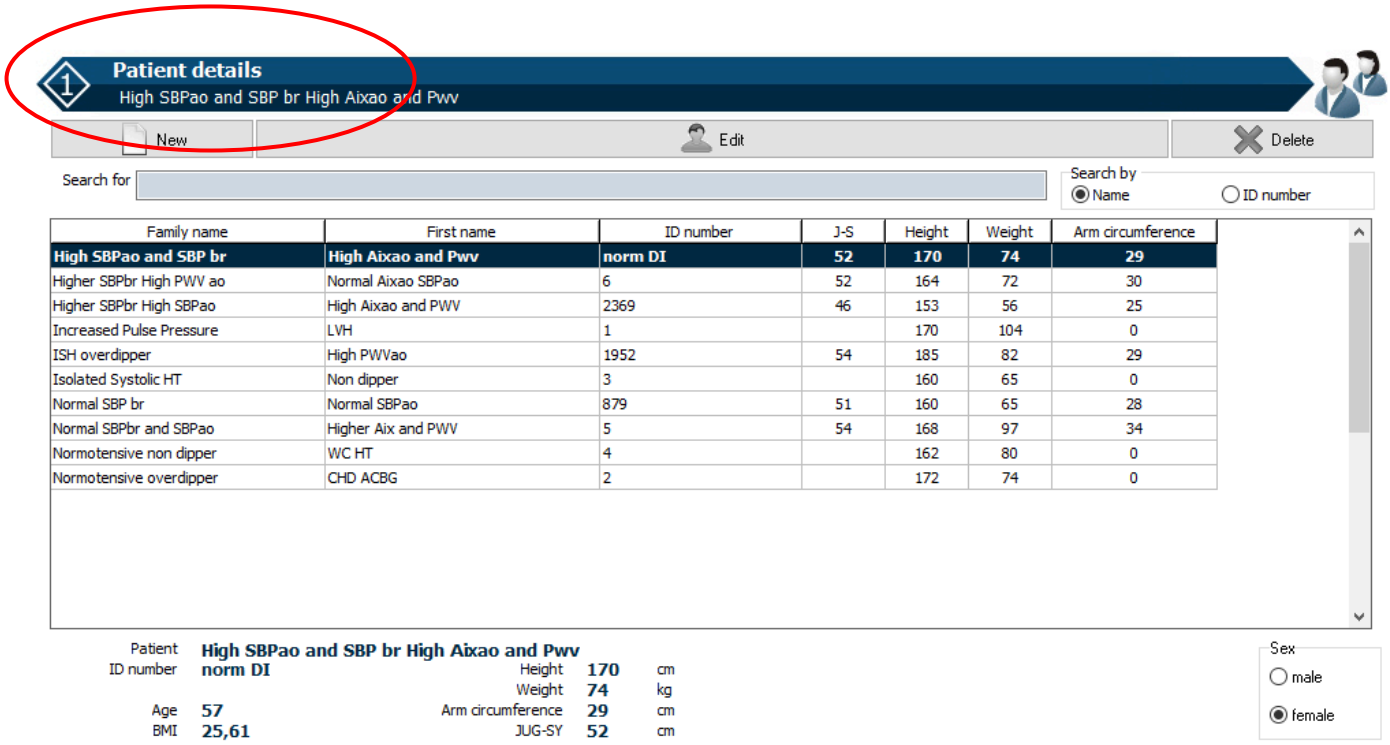
2. Login

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



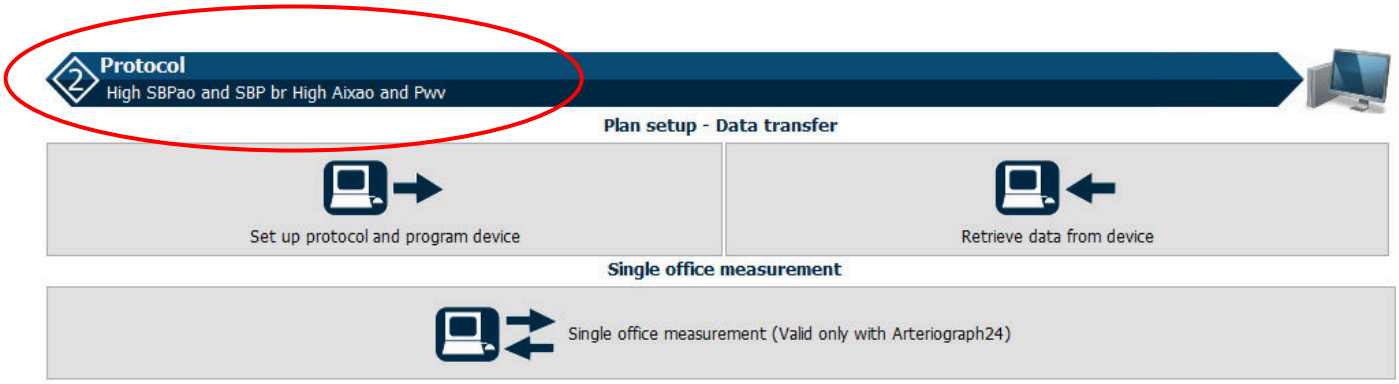
3. Control panel

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



4. Patient's sheet

2. In the second module you can find functions for communication with the device, i.e. programming the device or downloading measured data from it.



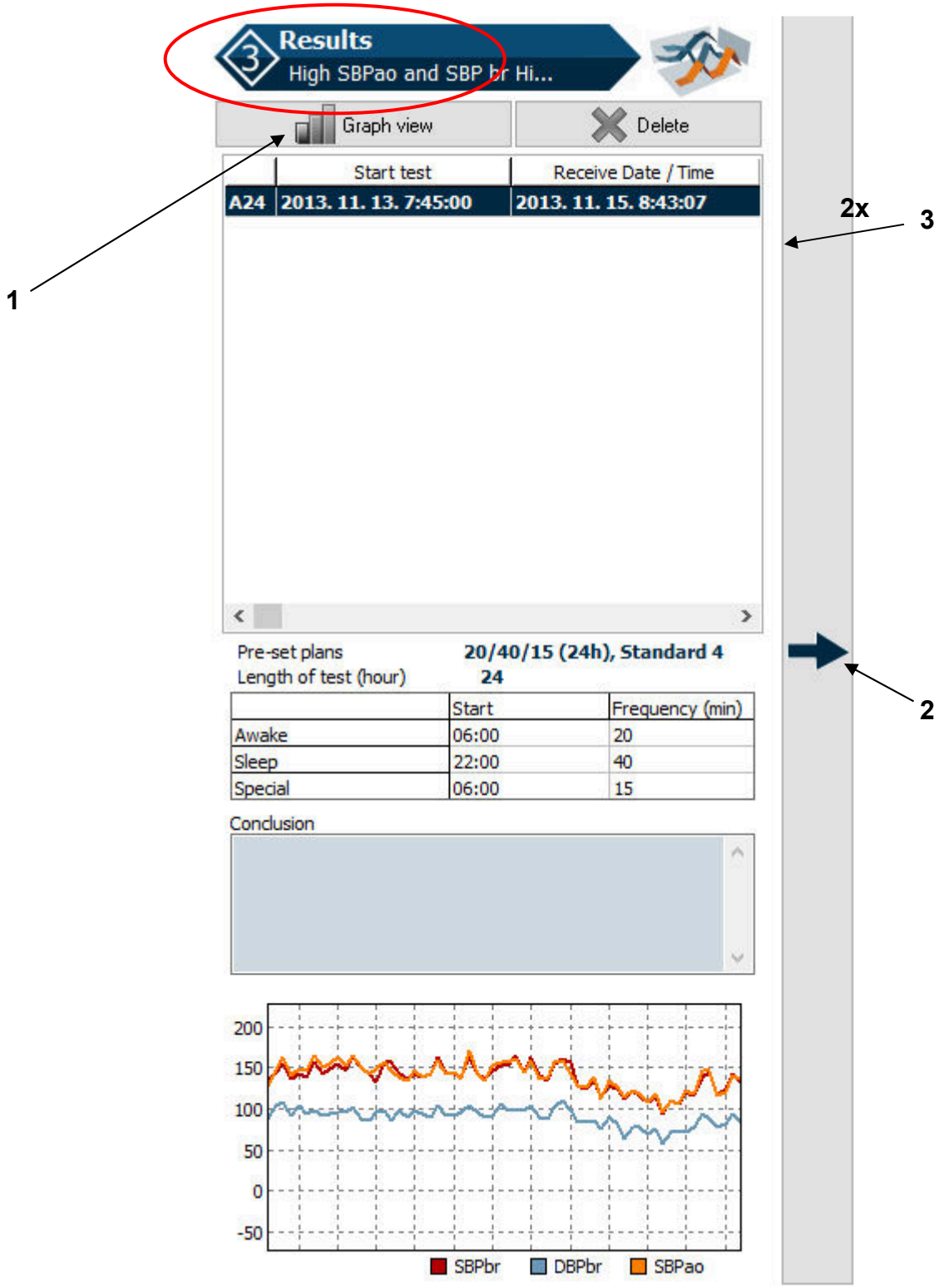
5. Measurement

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

Selection can be done by:

1. Clicking on the required measurement and select “Graph review” button.
2. Clicking on the required measurement and select the “Onward” button signed by an arrow on the right.
3. Double click on the required measurement.

Either way, the result is the same: the required measurement will be displayed.



6. Selecting measurements

3.3 The main menu of TensioWin™

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

File

Import data file: Interpreting a TensioWin™ datafile previously saved by TensioWin™ or received by e-mail.
Export data: The data of the selected patient can be exported for further analysis
Import from a database: To import previously saved TensioWin™ database
Backup database: Backup database for safety purposes by selecting the destination directory for the backup file. When starting the software a warning massage will pop up if there had been no backup in 30 days.
Exit: Escape from 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.
Patient functions: display or hide the available functions of the selected Patient (new, edit, delete)

Operator

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

Change Operator: By changing the login name, it is possible to operate amongst the given patients and measurements, without actually exiting the program.
New: A new login/physician can be added by clicking this menu item.
Edit: The data of a selected physician can be edited here.
Delete: Data of a selected physician can be deleted here.
Allocate patient: The patients belong to other operators can be allocated to the current operator

Patient:

By clicking on this menu item you can add, edit or delete patient data, calculate cardiovascular risk and print report.

New: A new patient can be added here.
Edit: The data of a selected patient can be edited here.
Delete: By clicking this menu item the selected patient can be deleted.

Device types

Search device:

The available devices around the computer can be found

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

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

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.

Setup

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

- you can set the target pressure of the device to a pre-determined starting value or to 50 mmHg above the previous MAP value
- you can determine the type of the cuff
- you can set the device to repeat the faulty measurements
- you can select or prohibit that the placing of the cuff should be checked by the device or not
- you can download the actual date and time into the device
- you can change language

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

Shall select the type of the device
Shall select the required communicational port

Information menu

Help files: This function provides you with help in using the software.
User's manual: The User's Manual can digitally be displayed. To use this function a program capable of reading PDF files should be installed to the PC.
Manufacturer and software version information: This function gives you information about the TensioWin™ software.

4. Using the TensioWin™ software

4.1 Operator's data

Add new operator/physician

If you want to add a new physician to the database go to menu "Operator – New" and enter the data of the physician 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 physician now appears in the list. It will also be listed in the login names list upon starting the software.

Selection of the operator

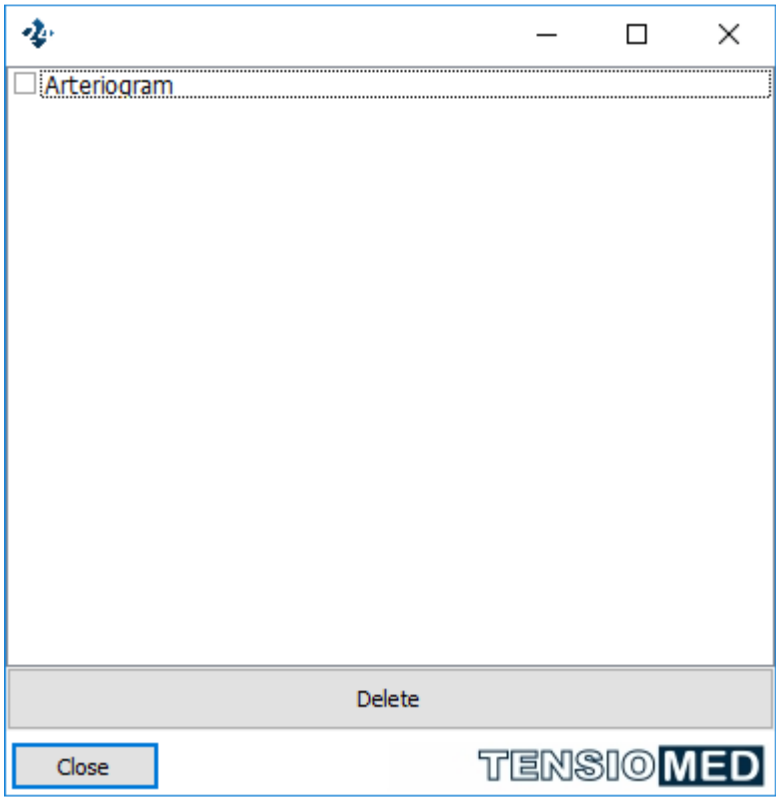
In case you intend to choose a different operator than the one which is already logged in, select the "Change Operator" menu item or select "Change Operator" from the drop down list of "Operator" in the main menu. Find the physician in the list and select it by clicking on the name and then clicking the "OK" button. The name of the selected physician is indicated in the title row of the window.

Edit operator data

If you want to modify or edit previously entered data go to menu "Operator – Edit". Modifications can be saved by clicking "OK".

Delete operator

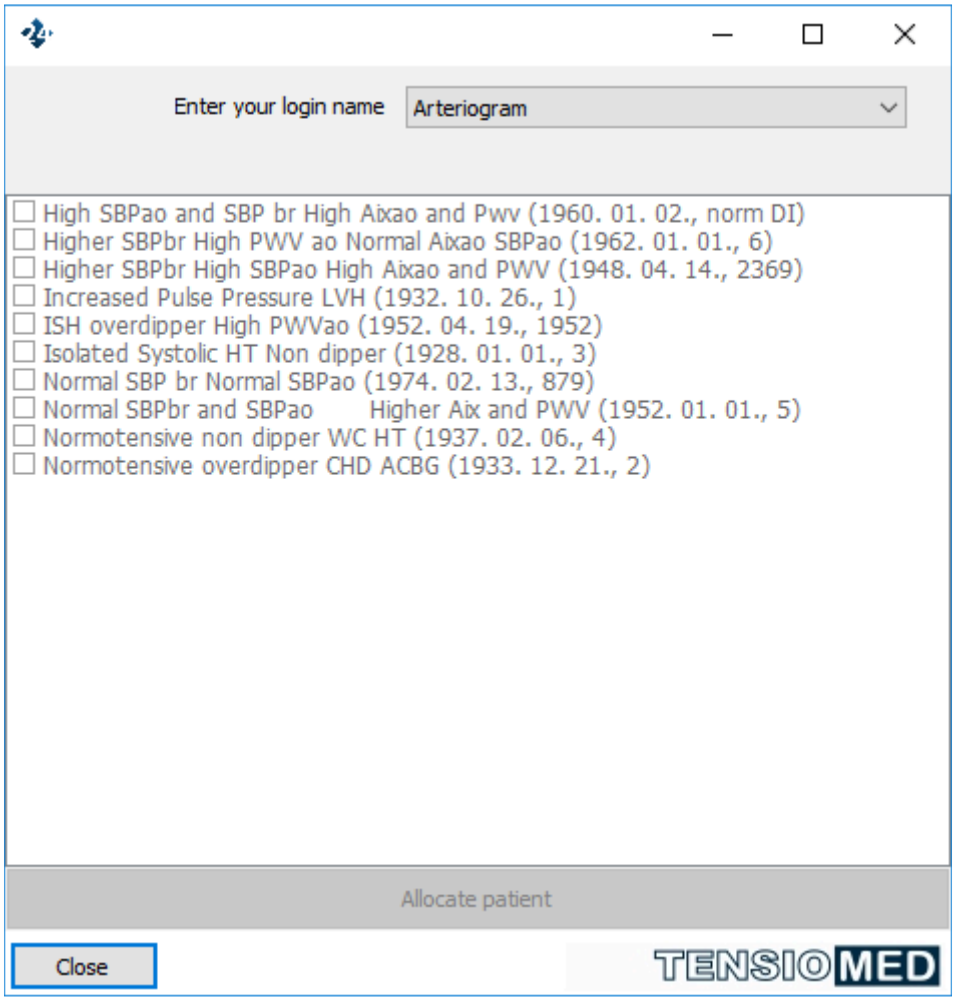
You can delete one or more operators at a time via the “Delete operator” menu item. Simply select the required operator and press “Delete” button. The action will only be performed if the password of the particular operator was given. To complete operation TensioWin software has to be restarted.



7. Delete operator

Allocate Patient

In case you would like to insert a Patient assigned to another Operator, select “Allocate patient”. From the pop-up window you can select to allocate the required patients only if you are aware of the assigned Operator’s password. To complete allocation, select the required Patients and press “Allocate patient” button.



8. Allocate patient

4.2 Patient's data

Selection of the patient

You can select any patient that belongs to the formerly selected operator/login name by using the patient list in the "Patient details" module of the main window or by using the search function above the mentioned list.

Hint: you can search for a particular patient of the physician by using the search function. You can search for names or ID numbers. To search for a name check "Name" in the "Search for field" and start typing the name of the patient. The search commences with partially entered names.

Add 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 setup of the database corresponds to the steps of a usual outpatient visit. This allows to enter information on medical history, on current complaints, on

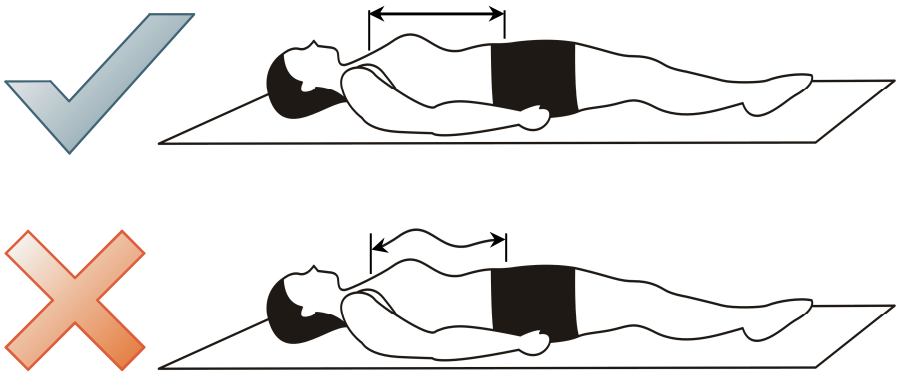
examinations, on laboratory data and to assess cardiovascular risk. You can save data by clicking “OK”. Comments or opinions given here are automatically added to the printed report. Please, note that the following colored fields have to be completed:

- Family name
- First name
- Date of Birth

In case of TensioMed TensioDayPlus™ and TensioMed Arteriograph24™ the following data must be entered:

- *JUG-SY (Jugulum-Symphisis distance)*
- *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).



Measure the suprasternal notch – pubic bone distance (Jug-Sy) with use of the supplied tape measure.

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 database 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 edited. 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 newest 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 readings to a particular patient’s database, select “New” on the Office BP panel on the Patient details window. Enter the systolic and 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 with 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 “OK” 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 bottom 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 data by clicking on the “Save” button. You can select the dimension of the values to be entered (e.g. mmol/l or mg/dl). After saving your work, 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 Previous- or 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 risk 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

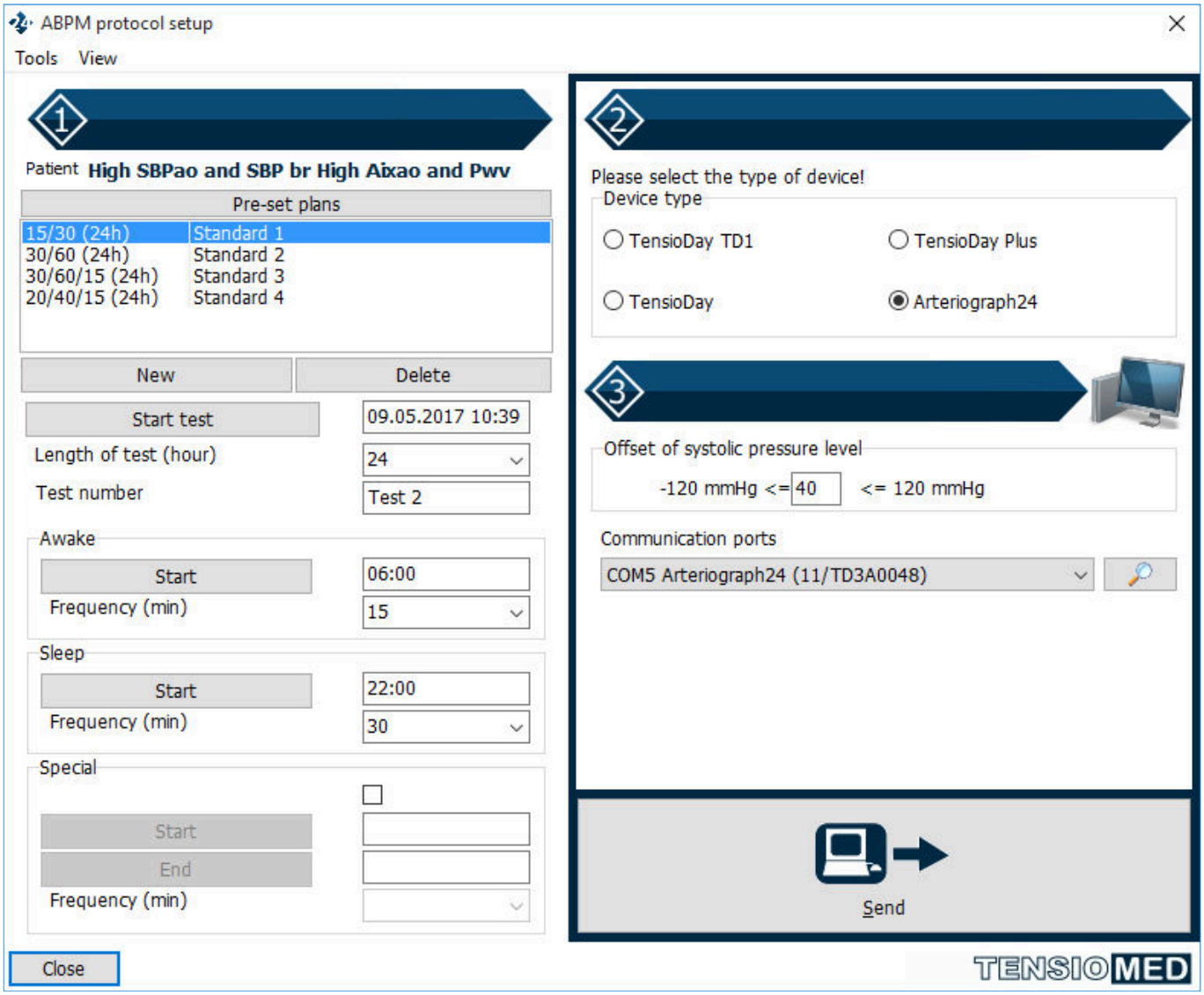
To set up a measurement protocol and to program the device, press the “Set up protocol and Program device” button on the second module.

9. 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:

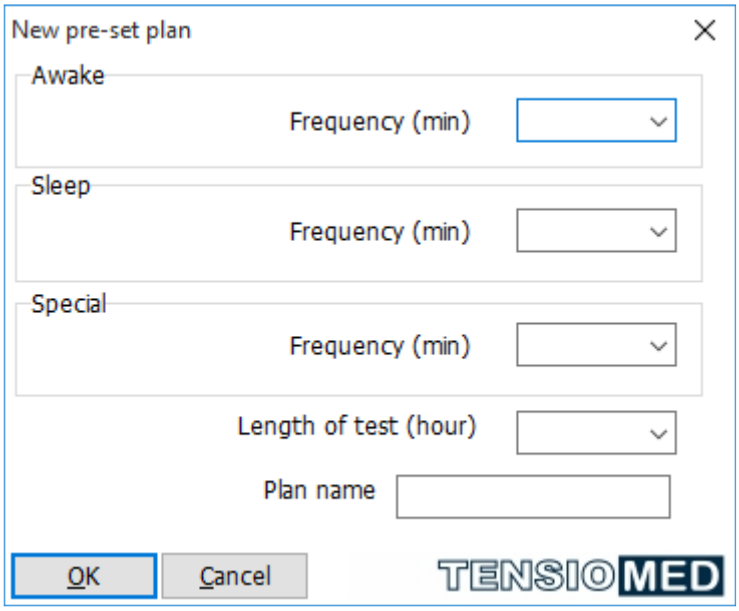
- the length of the test
- the **active** (awake), the **passive** (asleep), and (optionally) the **special** periods. This latter may be needed if there is a period of special interest (e.g. early morning hours before awakening) during which you want different measurement frequency
- the measurement frequencies during the active, passive (and, if included, special) periods
- the starting time of the test and the different periods



10. 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; the second number to the measurement frequency during the passive; and the third number to the measurement frequency during the special period, respectively (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.



11. 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.

In case the communication port is not known, but we intend to define it, then click on the search button next to the available communication ports or close the window going back to the control panel and select the “Search device” button on the toolbar. This way we can monitor the examination of the COM ports existing on the computer. Where the software finds a related device it reveals the name of the device next to the port, i.e. “COM3: TensioDay3”. Thereafter the selection of the required device is possible from the drop down list. Warning! Make sure that time is displayed on the screen before communication starts; neither “BLUELINK” or “CONNECT” – in case of Bluetooth® communication – nor “IrDA” or “CO PC” – in case of infrared communication - should be seen.

If known, the number of the communication port can also be selected. This action can be omitted as the software automatically detects the correct port and stores its number so it does not have to be searched for next time. When selections are made, click “Send”.

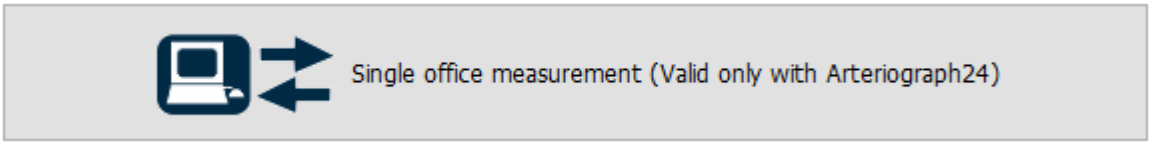
In case there are more devices available, but only one is intended to be used – of which the communication port is known – TensioWin™ is capable of connecting only via the selected communication port. This way the automatic search can be avoided and it is impossible to re-program another device connected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

The process of download of the measurement protocol to the device can be followed on the progress bar. “CONNECT” - in case of Bluetooth® communication –or “CO PC” – in case of infrared communication - 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”.

5.1. Arteriograph measurement

From the TensioWin™program it is possible to start a single Arteriograph measurement without prior programming the device.
This function is only available for Arteriograph24. To start the Arteriograph measurement, push the "Arteriograph measurement" button in the control panel field 2:



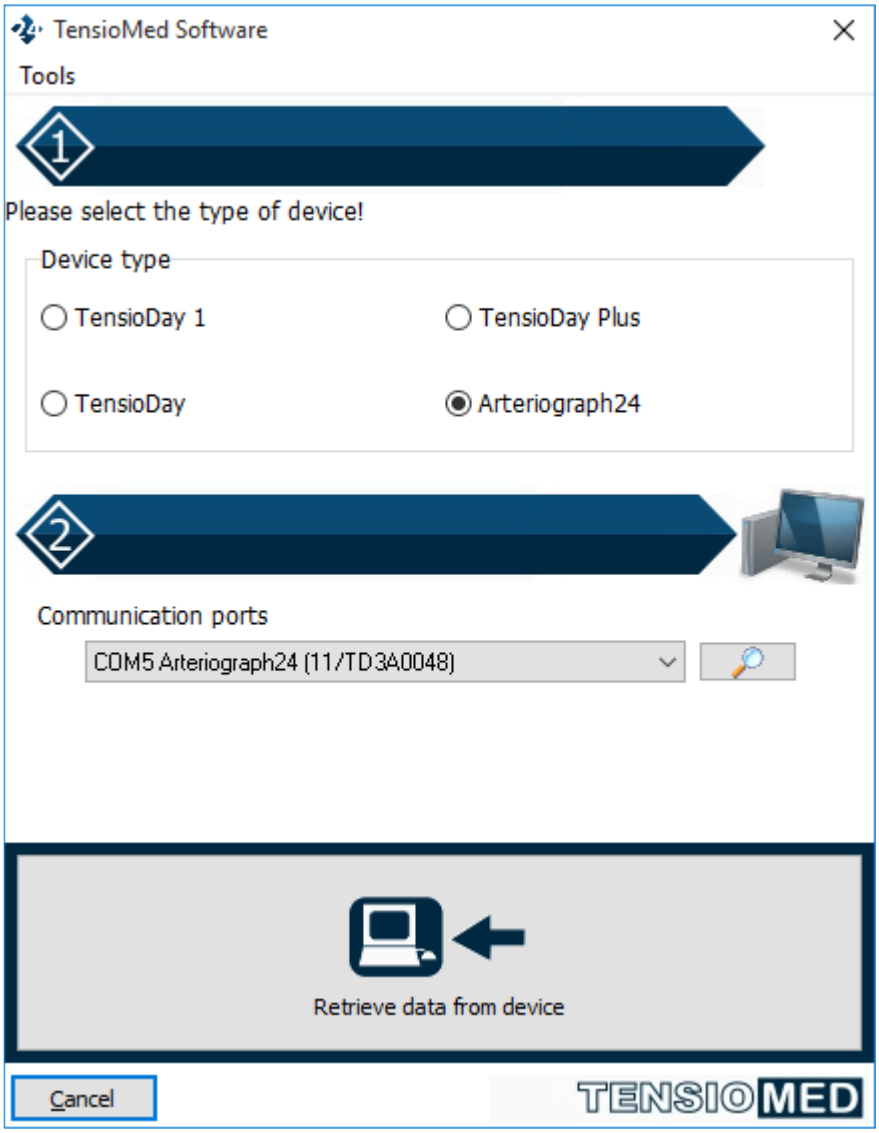
A device selection window will be displayed after the patient has been approved.
The measurement can be started with the "Start" button. An information message will be appearing first about the recommended cuff size to the patient’s arm circumference.
Attach the appropriate cuff to the patient. The "OK" button starts the measurement.
During the measurement process, an information window is displayed while the Arteriograph24 performs the measurement and forwards the result to the TensioWin™ program. After the results have been received, the evaluation window will be displayed with the registered results. Here is an opportunity to evaluate, print, and send report by an email.
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 TensioMed® device into the computer select the “Retrieve data from device” button in the second module.

12. Retrieve data

The pop-up window for device selection appears:



13. Selecting the device and the communication port

As several TensioMed® products can be managed by the TensioWin™ software the proper type of the device and connection port have to be selected when initializing data transmission (see also above).

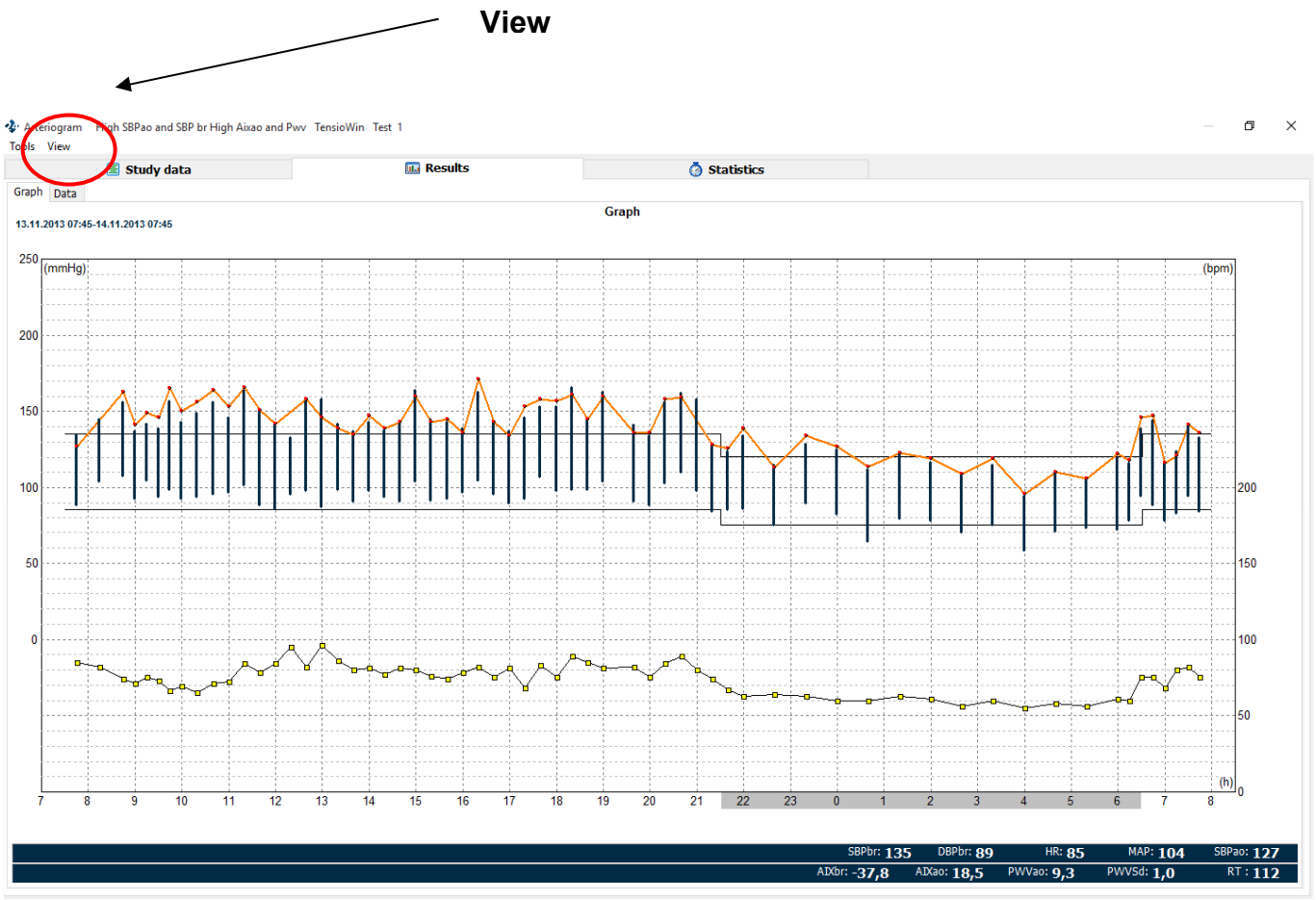
In case the transfer of data is intended to be done from a computer different from which the device was programmed to or the device was programmed via the device button – TensioDay2, TensioDay 3 – from the drop-down list of the "Tools" menu the "Downloading measurements of current patient to the PC" option should be selected to connect the transferred measurement to the preliminary selected patient. If you didn't select this checkbox, the software will not realize any defined measurements in these cases.

Please note that, in case the measurement was registered on the PC before, then the current patient's test in progress – if there is any – will considered to be completed, thus no more measured data will be added. The measured data will appear in a separate measurement of the patient. Once a test is considered to be completed it cannot be resolved.

It may happen that you would like to retrieve data of another Operator's patient. In this case you can complete data transfer by using the required operator's password during the process.

The process of data transfer to the computer can be followed on the progress bar. The successful transfer is confirmed.
After successful data transfer the blood pressure values are ready for analysis.

NOTE: You can transfer the blood pressure data any time during a particular ambulatory blood pressure monitoring test. This may be necessary, for example, if you want to check the performance of the device or see the blood pressure values while the test is in progress. The data transfer does not affect the set protocol, and after data transfer the test will resume until the set length of the protocol is completed. If you transferred data while the test was in progress, i.e. before the full length of the test was complete, this fact is shown in the "Status" window of the first page of the "Analysis". If you transfer additional data from the same test (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.



14. **Largest view of the Analysis page – hiding all the possible parts**

7. Analyzing data, evaluating measurements

In the third module of the main page select the required test from the list of the given patient.

The Analysis page can be personalized for the purpose of easier usage. Selecting “View” from the main menu you can hide and display certain parts of the window, ensuring the larger view for evaluation. This way you may reduce the apparent data for the blood pressure curve only, while all the main functions are still available from the main menu.

These functions are available via **Tools** in the main menu

Export
The complete measurement results can be exported from here and can be evaluated later on by another software in chart form.

Save
The measurement can be saved as a special data format in order to be portable and readable in another TensioWin™.

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

Save and send
This is a complement to the previous “Save” function with a further option for sending e-mails including the saved measurement together with the “standard report”.

Print
To print the measurements. It can be done either in the form of “Standard report” or a selection of the printable reports can be prepared as well.

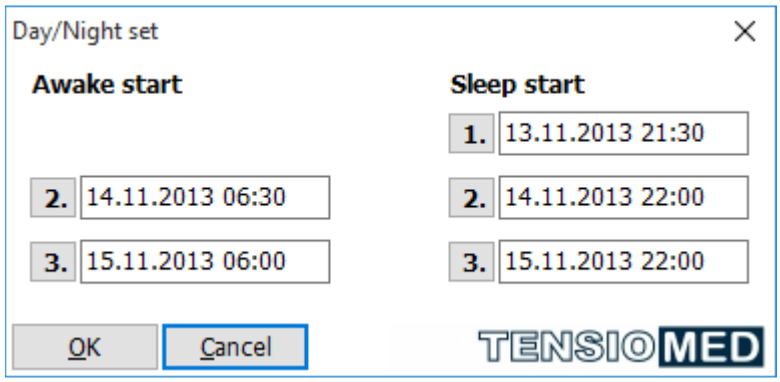
Return to the main device menu screen
It closes the present measurement and leads back to the control panel, where a new measurement can be selected, launched or the User can quit the program.

The three pages of analysis:

- **the “Study data”**
- **The graphical page of “Results”**
- **Page of “Statistics”**

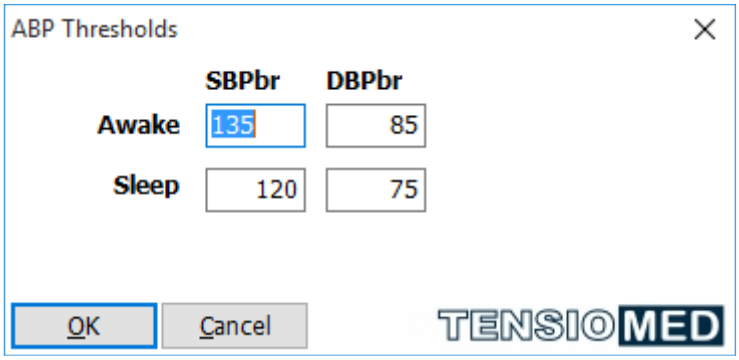
7.1 The Study data contains the main specifications and the status of the measurement protocol (in progress/completed), besides the patient's data.

During analysis, the active and passive periods can be changed subsequently the test, both for statistical analysis and for graphical review. It can be necessary if the patient didn't observe the preliminary set "Sleep" and "Awake" periods. Selecting the "**Day/Night set"** buttons you will see as follows:



15. Setting Day/Night

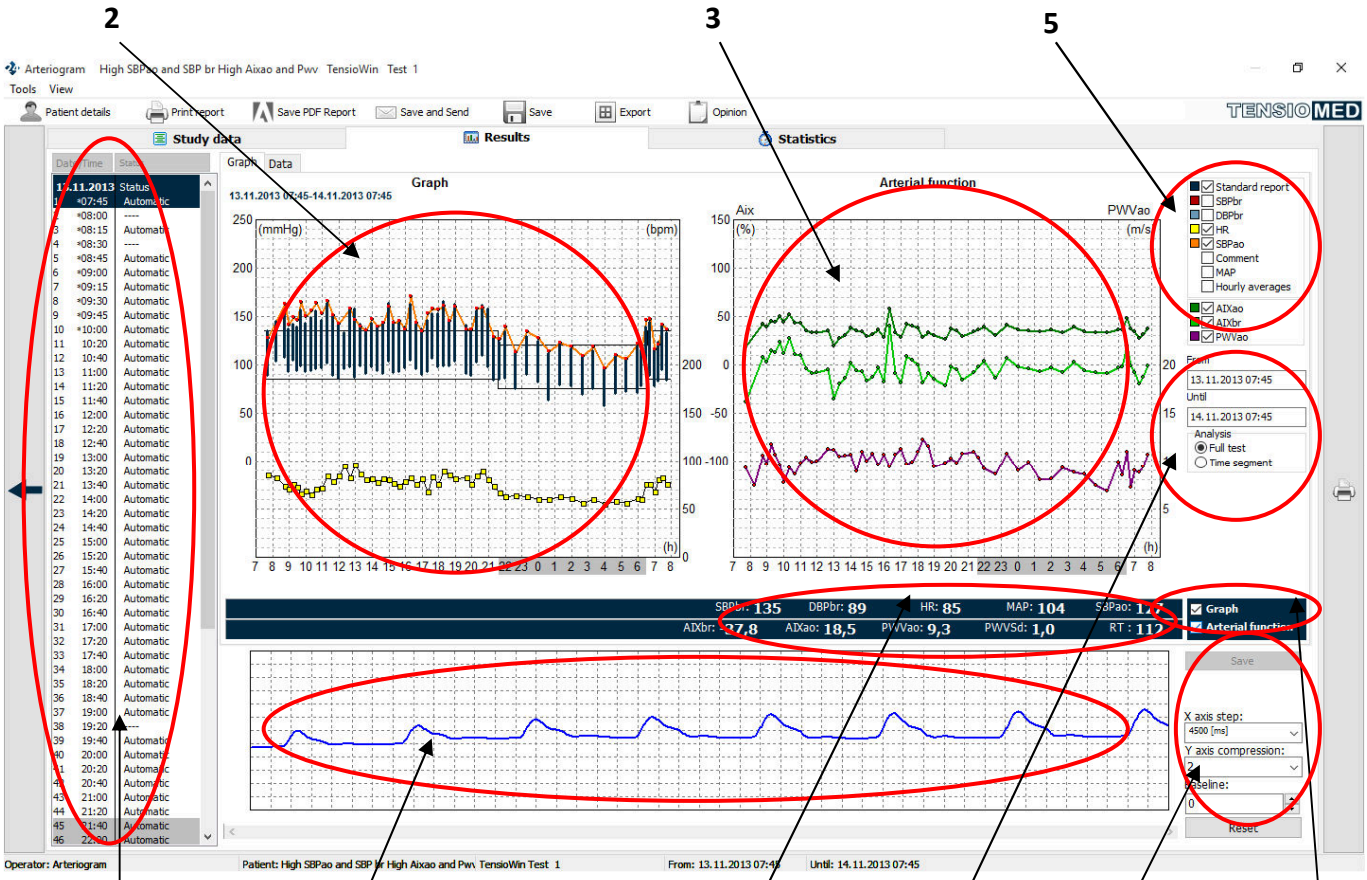
If you change the start- and endpoints of the active and/or passive periods, then the graphical review of the analyzed data will be based on the modified time setting.
The target blood pressure values can also be changed here selecting the "ABPM thresholds" button.



16. Setting the thresholds

TensioWin™ software will reveal this threshold by a continuous black line on the blood pressure curve.

7.2 The graphical page of results, displaying also the measurement results numerically



17. The graphical page of Results

Containing two additional pages:

The Graph page

The signs of Figure16 are as follows:

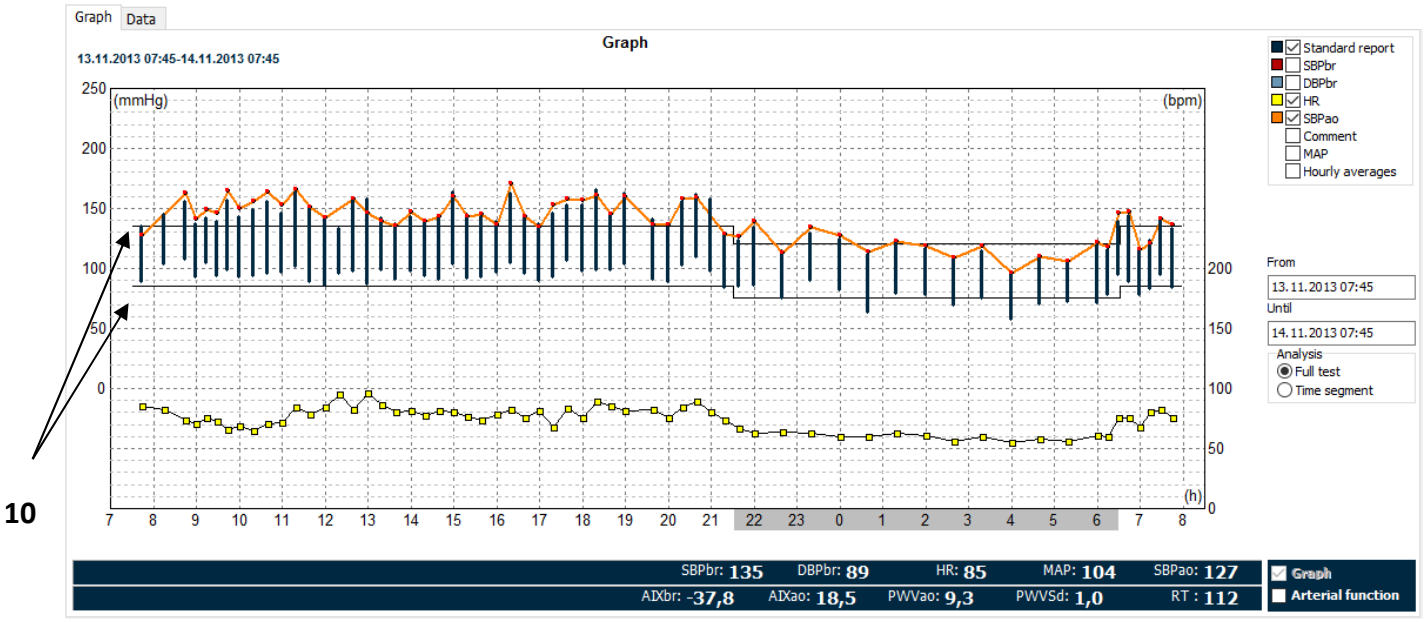
1. Standard Measurement list
2. Blood Pressure Curve
3. Arterial function Curve
4. Blood Pressure Curve/Arterial function display/hide
5. Select the display parameters
6. Select the display period
7. Numerical display of the given measurement
8. Pulse wave Curve
9. Settings of the Pulse Wave Display

Standard Measurement list (1)

The measurement list helps the better coordination between the measurements of a given patient. By clicking to a specific measurement, a red, vertical line appears on the curve, showing the required measurement, its numerical data (7) below and the corresponding Pulse Wave Curve* (8). The reverse is also true. Clicking to a specific measurement result on the blood pressure curve will change the focus of the measurement list as well – and reveals the Pulse Wave Curve.

**In case of Arteriograph24*

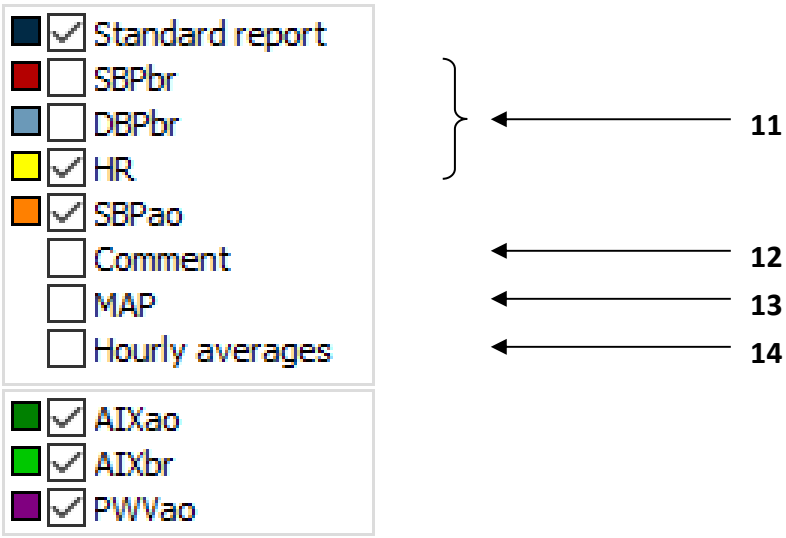
Blood Pressure Curve(2)



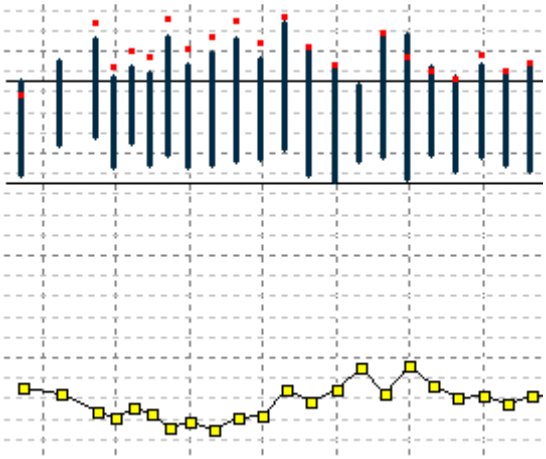
18. Blood Pressure Curve

The graphical display of the measurement data as a function of time 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 lines (10) (note that 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 circle on the top of the graph. There are several options for the graphic display:

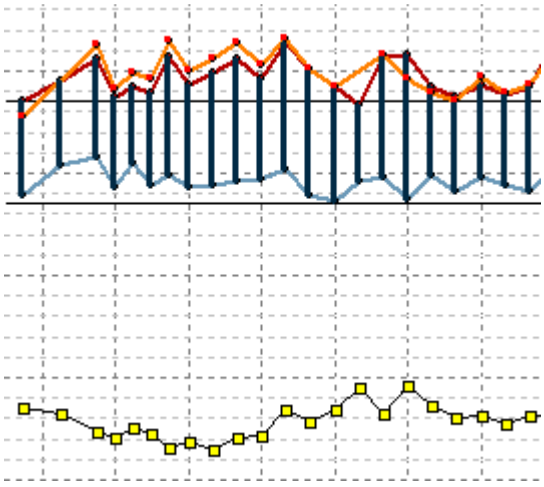
- the readings may be displayed either as individual bars or the systolic and diastolic values connected by a solid line (Figure 19-20) (11)
- the comments typed in on the 2nd page can be displayed (12)
- you can have the mean arterial pressure for each reading be displayed (13)
- you can view either the individual measurements or the hourly averages (14)
- you can view either the full test period or only a time segment of it. Clicking on “Time segment” at the bottom of the page allows you to define the time segment to be displayed (6)



19**. Editing the graphical display**



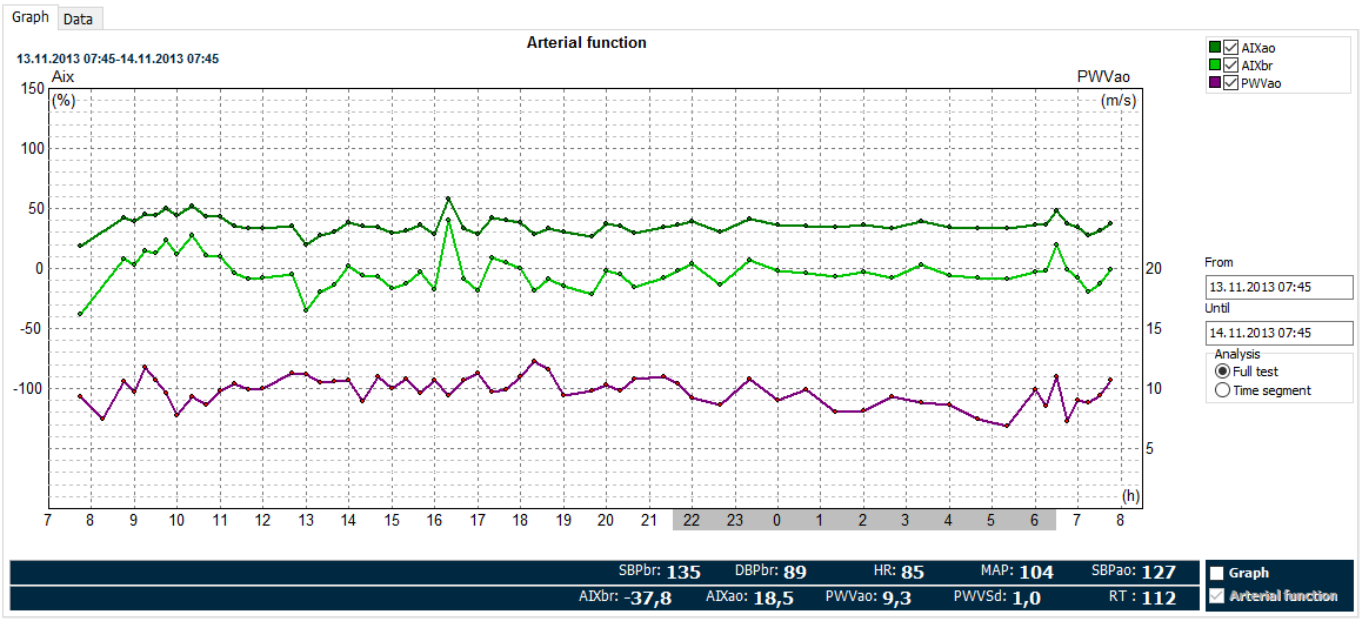
20. Without connection



21. Connected by a solid line

Arterial Function (3)

The graphical display of the arterial function as a function of time can be displayed here. It is all the same as for the Blood Pressure Curve that both the threshold values and the start and endpoints of the active and passive periods can be modified at the “Study data” page.



22. Arterial function

The Aix-ao, Aix-br and PWV-ao parameters can be displayed or hidden.

Thus it is possible to evaluate the standard arterial function parameters and the data measured by Arteriograph24 either in parallel or separately. It can easily be done by clicking on the checkboxes above the graph: “Graph” and/or “Arterial function”.

The different curves can be displayed or hidden. (The parameters of SBP-ao TensioDay Plus, SBP-ao, Aix-ao, Aix-ao, Aix-br, PWV-ao can only be displayed in the case of Arteriograph24)

Pulse Wave Curve

The 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. The required extent of the amplitude can be set by clicking the “-“ and “+” buttons next to the curves. As a default, the software evaluates the curve, but it is still possible to evaluate manually. 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 let the button off. TensioWin™ software automatically tries to evaluate the given section, 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, then the newly activated “Save” button must be selected.

The Data page

The Data page is the tabulated list of the time, the date and the measurement data (blood pressure, heart rate, pulse pressure). Threshold values, based on which some of the statistics are calculated can be modified by clicking on the Blood Pressure threshold button at the bottom of “Study data” page. The passive period is indicated by the shaded area and the special period by an “*” at the beginning of the row. Re-defining the start points of the active and passive periods will not change the marks of the data at the tabulated list. The status column indicates whether the reading is the result of an automated or 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).

While the blood pressure measuring algorithm 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 edit or delete 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 delete only the parameters of arterial function (“Delete Arterial Function parameters of the measurement”).

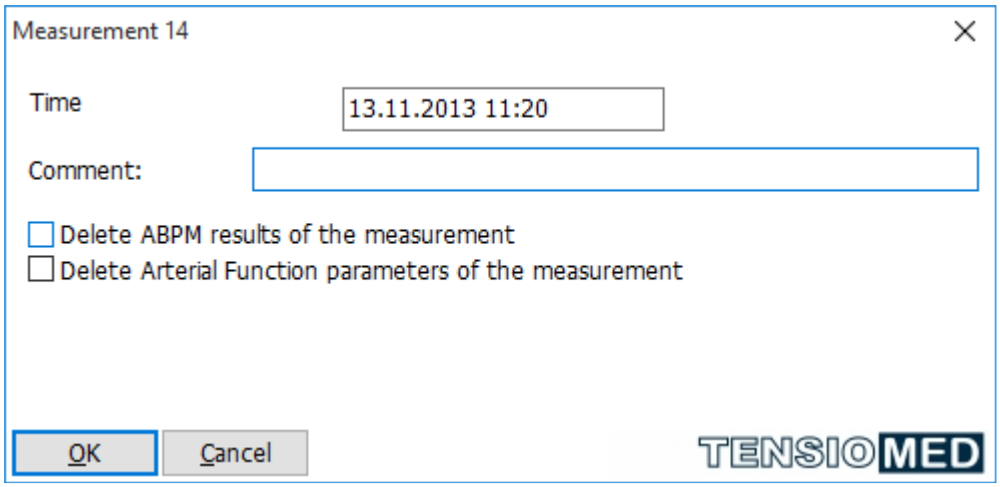
Graph | Data

13.11.2013	SBPbr	DBPbr	MAP	PP	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	
4	08:30	----	----	----	----	----	----	----	----	----	----	----	----	False measurement (A)
5	08:45	156	108	124	48	74	163	41,7	8,1	55	10,6	0,3	98	
6	09:00	137	93	108	44	71	141	39,0	2,7	48	9,7	0,7	107	
7	09:15	142	105	117	37	75	149	45,1	14,7	44	11,7	0,3	89	
8	09:30	139	94	109	45	73	146	44,2	12,9	52	10,7	1,2	97	
9	09:45	157	99	118	58	66	165	49,6	23,7	66	9,6	0,9	108	
10	10:00	143	93	110	50	69	150	43,7	12,0	57	7,7	1,6	135	
11	10:20	149	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	
19	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	

23. Data

By doing so, the standard hemodynamic parameters will appear on the blood pressure curve, but the arterial function parameters will not.
The temporarily deleted parameters neither will 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.



24. Editing results

7.3 Statistical analysis is shown on Statistics page

The statistics window contains 3 pages:

The Statistics page gives you the summary statistics of the test. You can define which period to be analyzed (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 re-defined. Temporarily deleted 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 re-define 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 re-define the threshold values, the PTE changes accordingly.
- Blood pressure load (Load) denotes the area under the blood pressure curve exceeding the threshold limit.

You can add the summary statistics of the different periods or time segments to the print list.

The Correlation page allows you to view the histogram of the monitoring data. Similar to the previous pages, you can define which period to be analyzed, 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 Histogram is a correlation plot of the systolic values as a function of the diastolic readings. You can display the plot separately for:

- 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" window.

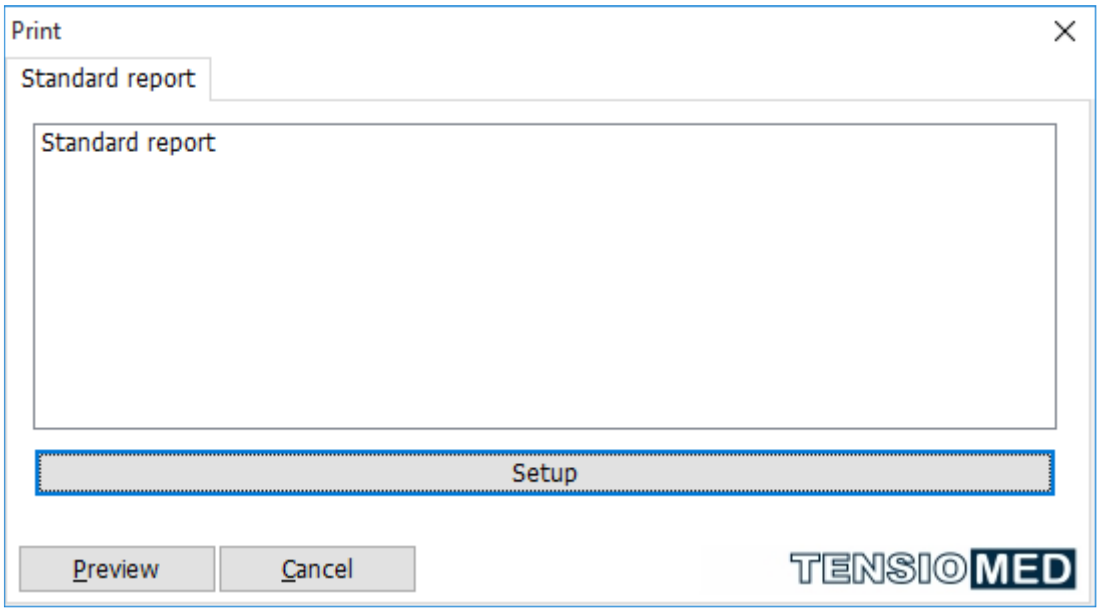
Similar to the previous page you can view the plot for either the full test period or only for a time segment of the test. Clicking on "Time segment" at the bottom of the page allows you to define the time segment to be plotted.

7.4 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 at the toolbar of Analysis window or the “Print” button at Tools menu, you can compile and print out the full report.



25. The print window

Standard report

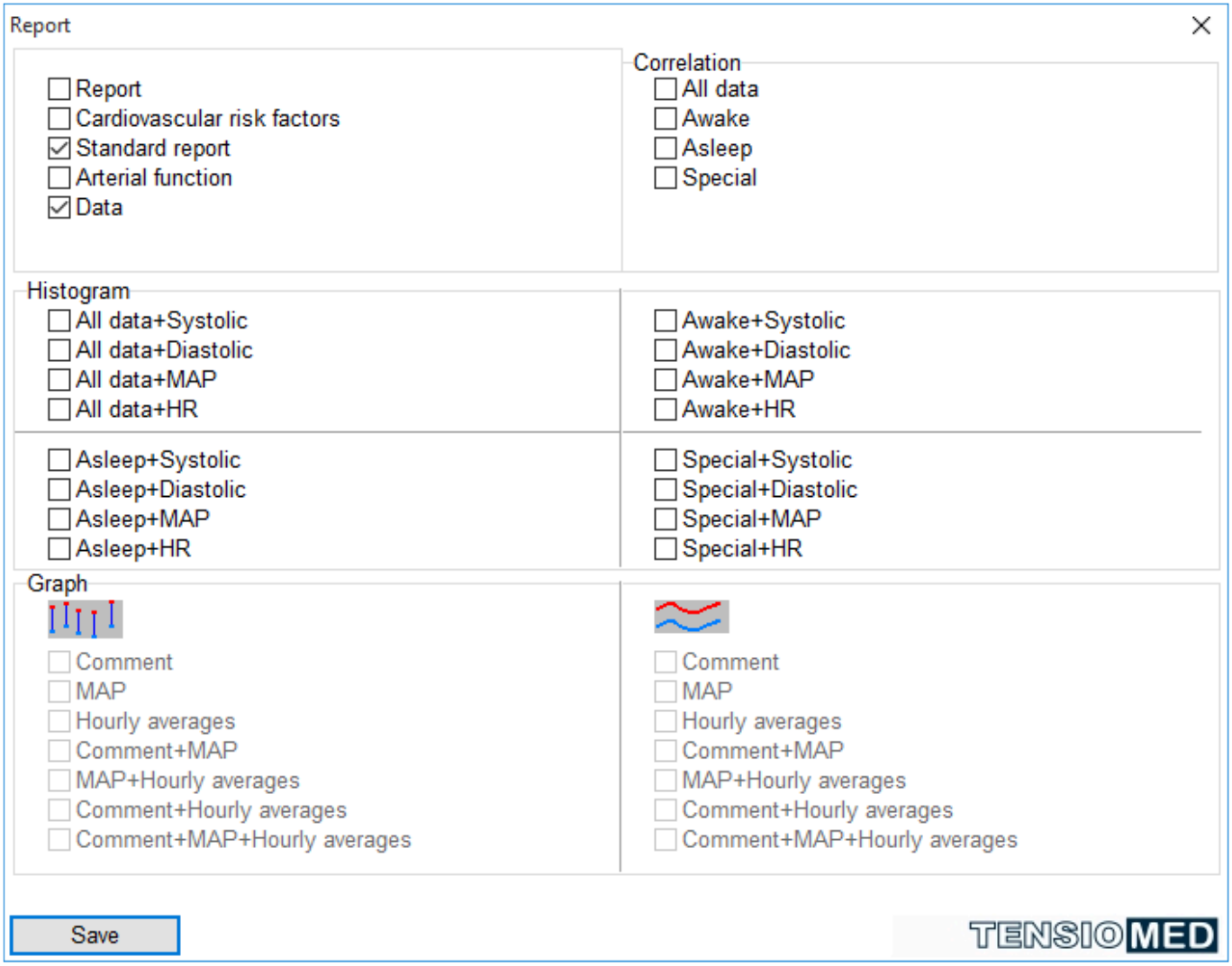
The generally used report form can be set here.
The default setting is as follows:

Standard report of 2 pages:

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

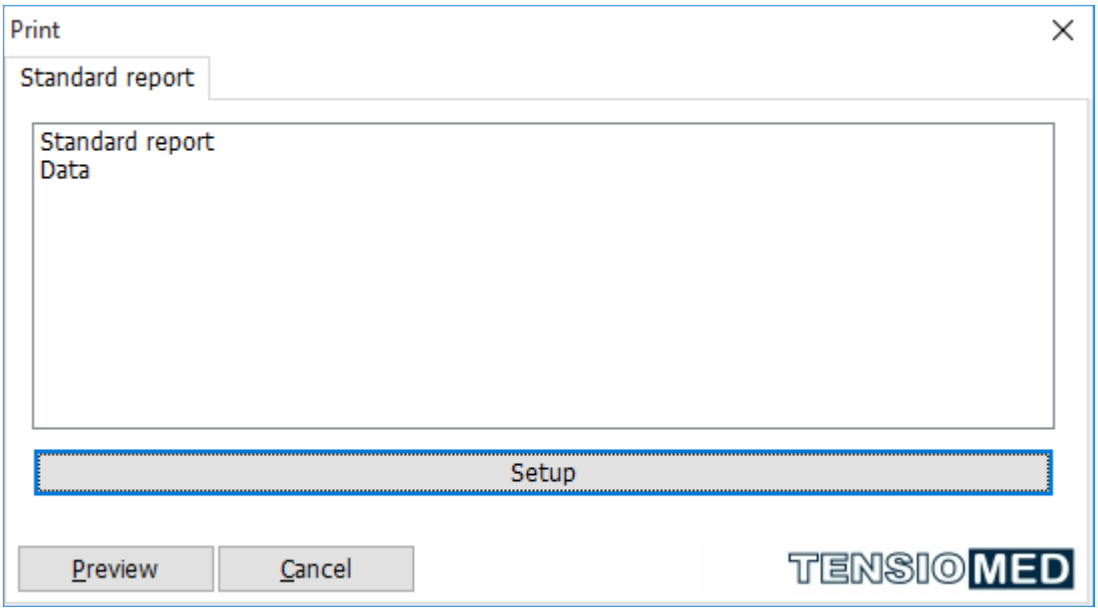
In the case of Arteriograph24, the standard report above is completed with the “arterial function” report, which contains the measured parameters of arterial function.

This setting can easily be changed by clicking on “Setup” and in the pop-up window you can select the parameters to be displayed on the default report setting.



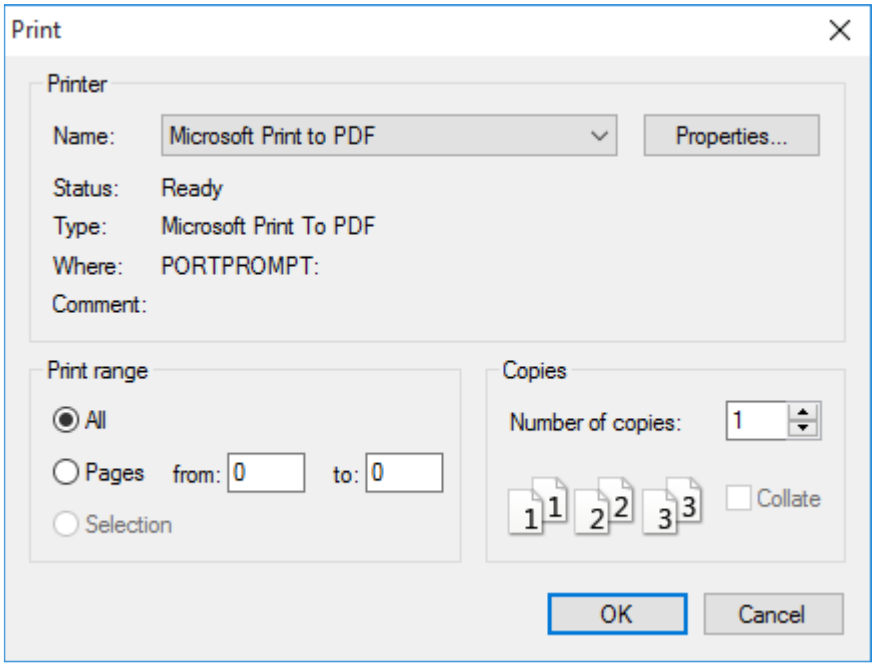
26. The settings of a required report

If “data” was added and you selected “Save”, the print screen will be as follows:



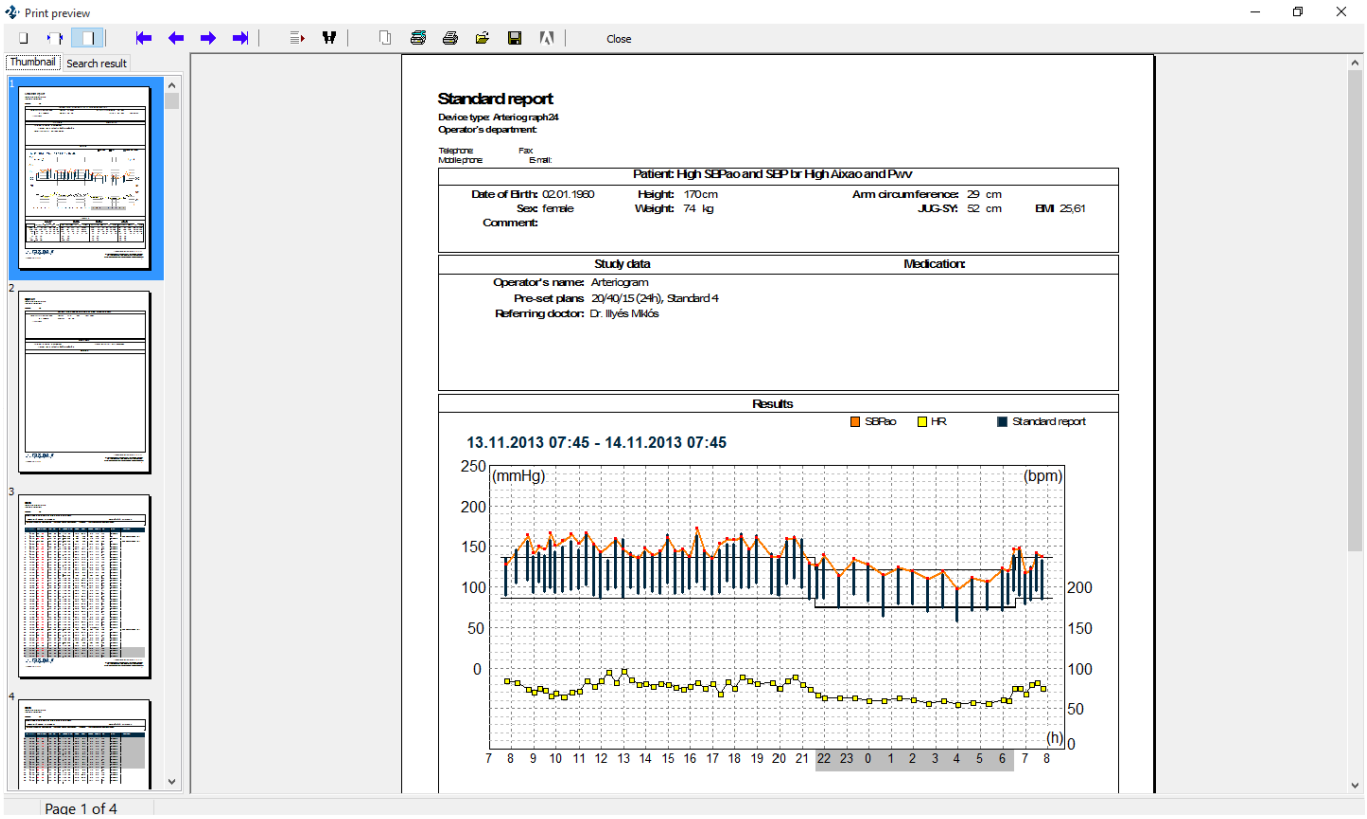
27. Completed report

After you set the required report for printing, click on “Preview”. Now the “print setup” window appears:



28. The print setup window

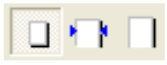
The required task and printer can be selected and configured here. If it is done, select “OK”, then the print preview appears.



29. Print preview

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

Zoom tool



The print preview page can be zoomed to fit the screen height (**Zoom to fit**), to fit the screen width (**Zoom to width**) and to the original size (**100%**).

Navigation tool

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

With use of these tools a search can be performed by page number (**Go to page**) or by a keyword (**Search for text**).

Print tool

The page can be printed with the previously determined settings.

Save/Load tool

The Report can also be saved in a file by clicking on **Save report**. The SW offers the patient ID as complemented with the current date and time as the file name. The destination directory of the saved file can be chosen.

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

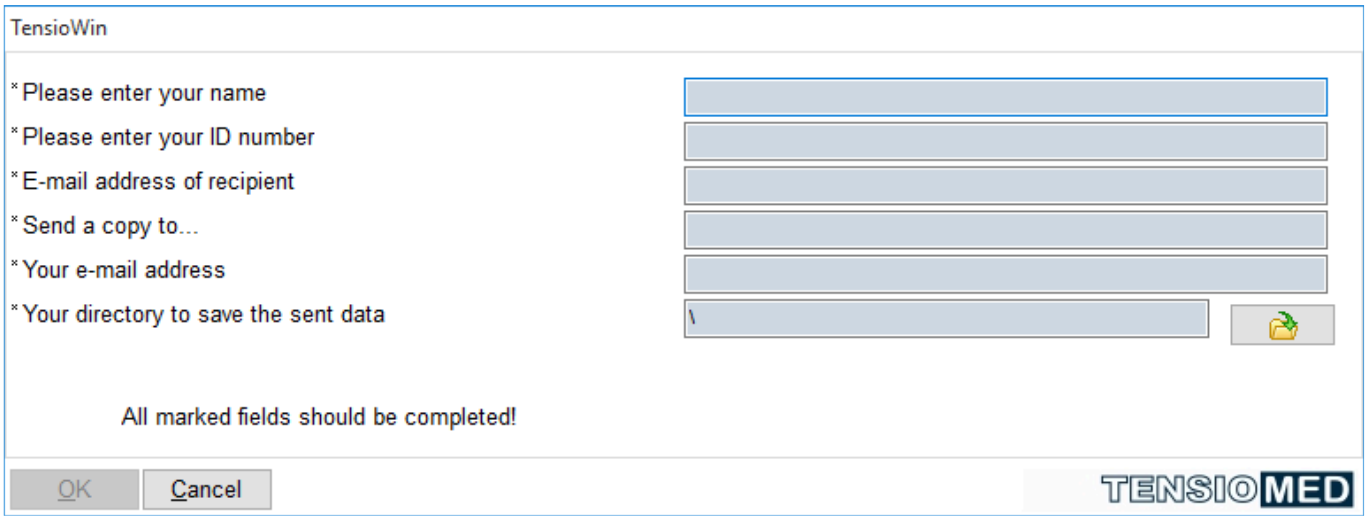
Save PDF report

The page can be printed in PDF format with the previously determined settings.

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

9. Forwarding a report by e-mail

It is possible with the TensioWin™ software to write a patient's full data relevant to a given examination into a file from the program's data base and send it in via e-mail to a certain address (with the general report in .pdf format) or to download a similar file into your program.

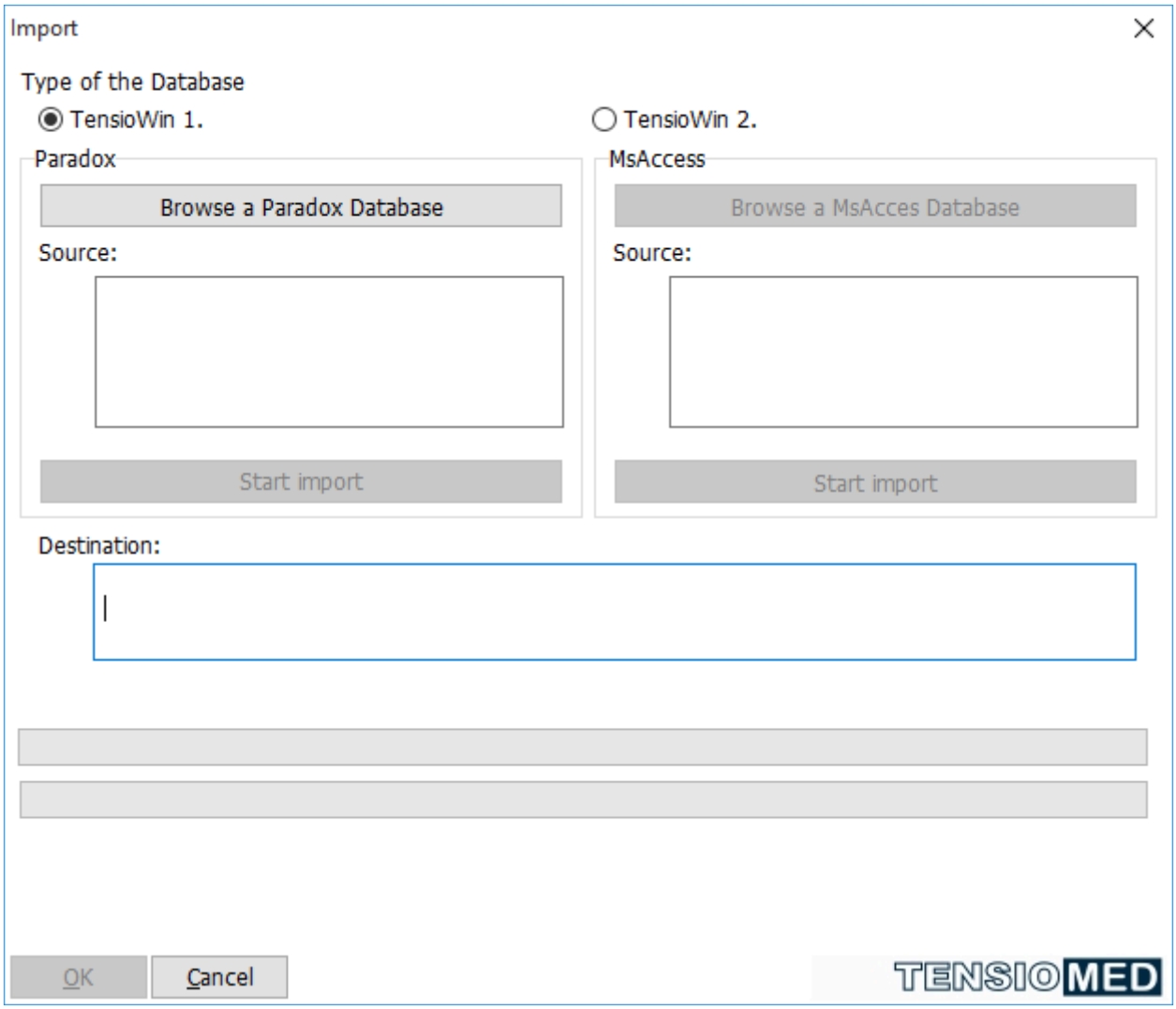


30. E-mail settings

This function can be operated by clicking on the mail icon on the top of the Analysis window. In case you use the function for the first time, the program will offer you a registration window, in which the colored fields must be completed because without knowing these data the e-mail cannot be sent.
After completing the fields, the software will save the file or report containing the data of the given examination automatically and it will display Microsoft Outlook or the basic corresponding program of the Windows with the completed data.

10. Import database

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



31. Import database

The process of importing a database is as follows:

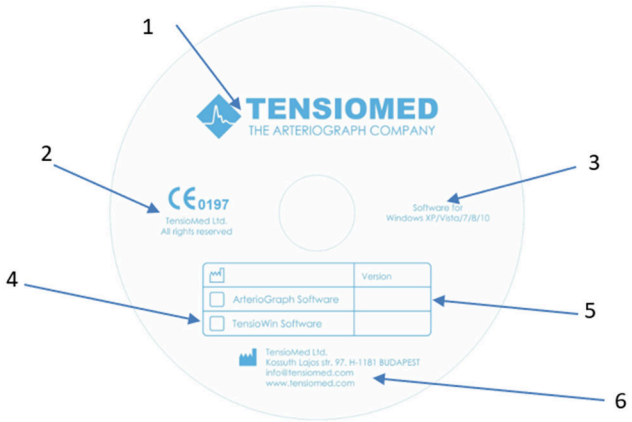
You can import database from File menu.
Select the type of software you intend to import (TensioWin™ 1. or TensioWin™ 2.)
The selected part of the window is always active. i.e. If you intend to import from TensioWin™ 1. select “TensioWin™1” button and click on “Browse a Paradox Database” giving the direction 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, you must restart TensioWin™ program.

11. Troubleshooting

Problem	Device type	Possible causes
No communication	TensioDay TensioDay Plus Arteriograph 24	• Communication adapter is not connected • The device is not recognized by the PC • No or low batteries in the device • The device was turned off
No SBPao values are displayed	TensioDay Plus Arteriograph 24	• Loose cuff • Arrhythmia • Tremor
No arterial function parameters are displayed	Arteriograph 24	
No print preview	TensioDay TensioDay Plus Arteriograph 24	No printer has been installed to the PC
The PDF report cannot be opened	TensioDay TensioDay Plus Arteriograph 24	Adobe Reader is not installed to the PC
Database import cannot be completed	TensioDay TensioDay Plus Arteriograph 24	Not the proper database was opened or the database was damaged
Cannot send e-mail successfully	TensioDay TensioDay Plus Arteriograph 24	• Outlook is selected at the e-mail settings but it is not installed to the PC • Standard e-mail is selected at the e-mail settings but no mail software has been configured on the PC

12. Labeling



32. CD printing

12.1. Explanation of the used symbols

1. The name of the manufacturer
2. The number of the Notified Body
3. The operating systems which the software can properly operate on
4. The name of the operating software (TensioWin Software in this case)
5. Version number (defined based on the current software release)
6. The data of the manufacturer

TENSIOMED®