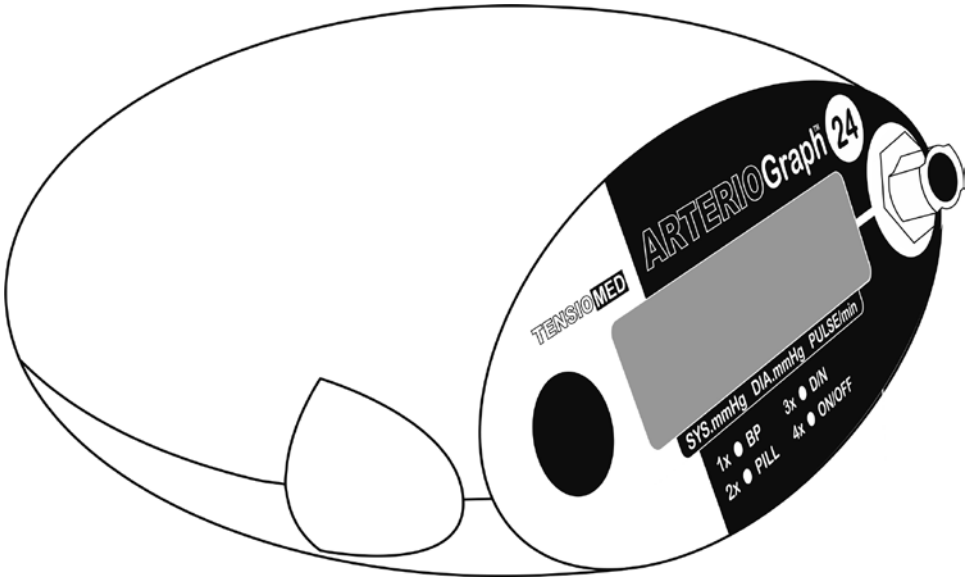
TENSIOMED
THE ARTERIOGRAPH COMPANY

ARTERIOGraph™ 24

Instruction for use

A device for 24-hour monitoring of arterial function (stiffness) and peripheral blood pressure, along with compatible software for Windows 10 or 11 operating systems.

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



CE 1639

TensioMed® ARG24TWIN-v01-00
Revised: 28-01-2025

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1. Introduction and the intended use of the Arteriograph24 and its software

The Arteriograph24™ device is designed to measure:

- Brachial blood pressure
- Heart rate
- Arterial stiffness parameters

It performs measurements over a period of 24 to 72 hours, using a non-invasive brachial cuff.

The device works with special software called TensioWin, which displays the results for blood pressure, heart rate, and arterial stiffness parameters. It is especially useful for patients who need detailed information about their arterial health, but for whom invasive methods are too risky.

Important Notes:

Professional Use Only:

- The Arteriograph24™ is designed for use by physicians and medical professionals. Patients cannot use this device at home without medical supervision. Interpreting the results requires advanced medical knowledge.

Device Limitations:

- The Arteriograph24™ cannot connect to other instruments.
- It is not suitable for patients with severe heart rhythm issues (like atrial fibrillation, bigeminy, or trigeminy) or severe tremors (like Parkinson's disease). In such cases, the device may not provide accurate results, though it does not harm the patient.
- It cannot be used on a wounded upper arm, or on patients undergoing certain medical treatments like high-frequency electrosurgery or hyperbaric oxygen therapy.

Pacemakers and Monitoring Devices:

- The device can safely be used on patients with pacemakers.
- Other monitoring equipment (e.g., ECG or oxygen sensors) does not interfere with the Arteriograph24™.

How It Works:

- The device measures blood pressure using the oscillometric method.
- The cuff inflates to a high pressure (above systolic blood pressure) and then deflates, which takes about 90 seconds.
- Measurements can be programmed to performed automatically at intervals (10–90 minutes) for up to 72 hours. Separate schedules can be set for daytime, night-time, or other periods.

Data and Reports:

- Data is stored on the device, which can save up to 1,000 measurements.
- Patients can start a manual measurement by pressing a button on the device. These manual readings are also recorded and displayed in the software report.

Why It's in English:

- English is the standard language for medical professionals worldwide. Translating technical terms related to arterial function could lead to misunderstandings in other languages. Therefore, the device manual and software are provided mainly in English to ensure clarity and accuracy.

Additional Information:

- Measurements and settings are transferred between the device and the physician's computer using Bluetooth.

The manufacturer, TensioMed Ltd., has ensured the accuracy of the information provided.However, future updates to the device or manual may occur without notice.

1.1. Contents of the manual

This manual is here to help you set up and get started with the device and the TensioWin software.

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

1.2. Supplementary information and helpful hints

Cleaning and Disinfection of the Cuff

- Cleaning and disinfection of the cuff sleeve should be performed as needed. For patient comfort and hygiene, a thin, light shirt can be worn under the cuff.

Recommended Disinfection Materials:

- Alcohol-based disinfectant
- Isopropanol (70%)

Instructions for Disinfection:

- Follow the manufacturer's instructions for using the disinfectant.
- Ensure the solution dries completely before reusing the cuff sleeve.
- Avoid using disinfectants that leave residue or are unsuitable for skin contact.

Important Notes:

- Do NOT disinfect the cuff bladder or the connected rubber tube.
- Some patients may have allergies or intolerances to specific disinfectants. For such cases or uncertainties, carefully wash off any potential residues.

Washing Instructions:

- The cuff sleeve can be washed in a washing machine at a maximum temperature of 30°C using a mild washing liquid.
- Do NOT use fabric softeners, disinfectant rinses, or textile deodorants.
- Avoid spinning the cuff sleeve during the wash cycle.
- Do NOT use a tumble dryer for drying.
- Ensure all disinfectant residues are completely removed through thorough washing before placing the cuff sleeve on a patient.

Important:

- The Velcro fastener must always be secured before washing.
- No residual disinfectant should remain on the cuff sleeve before it is used on a patient, especially if the cuff is to remain in place for 24 hours or longer.

Handling, Storage, and Transportation:

- The handling, storage, wrapping, and transportation of the device comply with general quality control requirements.

Compliance Standards:

This device meets the requirements of:

- IEC 80601-2-30:2018 - Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.

1.3. Warranty

TensioMed Ltd. offers a **2-year warranty** for a brand-new device. Any repair and device calibration within or beyond the warranty period are performed by TensioMed Ltd. in the service station of the company (Cziráki Street 26-32, Building A, 44/b, Budapest H-1163, Hungary). The **service life** of the device is **8 years.**

The instrument does not require regular maintenance during use. However, it is recommended that the instrument be sent to the service station of the manufacturer (TensioMed Ltd.) every 18-24 months for calibration and every 3 years for examination.

Warning! The procedures described above can only be performed by the manufacturer! If the operation of the device is faulty in any way, please contact our customer service (contact information below). We ask you to not try repairing the device or have it repaired at any other service station!

Central office and service:

TensioMed Ltd.
Cziráki Street 26-32
Building A, 44/b
Budapest H-1163
Hungary
Phone: (+36) 70 886 7337
(+36) 70 315 6197
Web: www.tensiomed.com
E-mail: info@tensiomed.com

1.4. General Information

We recommend carefully reading this user manual to familiarize yourself with the instructions and precautions.

User Requirements:

- Users should be able to read, understand, and learn the contents of the user manual.
- When using the TensioWin software, users need to understand the messages and labels within the software interface.

Basic skills required:

- Fitting the cuff properly onto the upper arm.
- Measuring the distance between the sternal notch and the pubic bone or the patient's height.
- Measuring the arm circumference.
- Operating the software on a computer.
- Performing the measurements does not require a medical degree, but only a licensed medical doctor is authorized to evaluate the results.

Age and Weight Considerations:

- The Arteriograph24™ is intended for use in patients aged 3 years and older, based on practical experience.
- There are no strict weight restrictions; as long as the cuff can be properly placed on the upper arm and the device can collect high-quality signals, it can be used on overweight or obese patients.

Note: In cases of extreme obesity, some measurements may be automatically excluded by the software.

- For very short or tall individuals, it is recommended to measure the JUG-SY distance (sternal notch to pubic bone) rather than relying on height measurements.
- The Arteriograph24™ is safe for use on pregnant women.

Battery Requirements:

- The Arteriograph24™ operates with 1.5 V alkaline AA batteries.

1.5. Device Usage and Safety Precautions

Storage and Handling:

- If the device will not be used for more than 2 hours, please remove the batteries to preserve their lifespan.
- Keep the device out of reach of children when not in use.

Special Patient Considerations:

- Be cautious when using the device on patients with serious mobility impairments, unconscious individuals, or those with coagulation disorders.
- Special care should be taken when using the device on children. They should not use the device independently.
- The device is not suitable for patients who are unable to remain still during measurements (e.g., due to Parkinson's disease or tremors). While this is not an exclusion criterion, movement during measurement can negatively impact the quality of the data.

Environmental and Disposal Recommendations:

- For devices that are no longer in use, please ensure they are disposed of responsibly to facilitate recycling and minimize environmental harm.

Usage with Proper Equipment:

- Only use TensioMed Ltd. cuffs with the device. Using third-party cuffs may lead to incorrect readings.
- If you suspect erroneous results, confirm the blood pressure measurement with auscultation.
- Avoid using a microwave device (e.g., mobile phone) near the unit when transferring data to a PC.
- Do not use the device in environments with mechanical vibrations (e.g., in vehicles) or strong sunlight.
- Extreme temperatures, humidity, or altitudes can affect the device's performance.

Maintenance and Safety:

- The device cannot be repaired during use. Do not attempt to disassemble or modify the device, as this will void the warranty and could lead to malfunction.
- The manufacturer is not responsible for damage or malfunctions caused by failure to follow these instructions.
- Avoid contact with fluids and minimize physical impact on the device.

- Be mindful of other medical devices on the same arm, as the pressurized cuff can interfere with their signals.
- The device should only be connected to the computer where the user software is installed. Using it on a different computer may result in an "Access violation" error.

Cuff Pressure and Duration:

- The device has an integrated safety mechanism that prevents the cuff pressure from exceeding 300 mmHg. If inflation continues above this level or lasts too long (180 seconds), disconnect the pneumatic connector and remove the cuff from the arm immediately.
- Too frequent or prolonged measurements can cause blood flow disturbances. To prevent this, ensure the device is programmed correctly to allow enough time for blood flow recovery between measurements.
- Avoid kinking the hose during the measurement process.

Contraindications for Use:

- Intravenous injections: Do not use the device on an arm that is receiving an intravenous injection.
- Blood coagulation disturbances: The device should not be used on patients with blood coagulation disorders.
- Post-surgery (artery/vein operations): If the patient has had surgery on an artery or vein (e.g., arterio-venous shunt) or has an intra-arterial catheter installed, do not use that arm for measurement.
- Radical mastectomy: If the patient has had a radical mastectomy, the cuff should not be placed on the same side where the surgery was performed.
- Skin conditions or wounds: If the patient has any skin disease, inflammation, or wound on the arm, use the cuff on the intact arm. If both arms are affected, the physician should assess whether the benefits of the measurement outweigh the risks.

2. The Arteriograph24 device

2.1. Explanation of symbols

The front view of the device is shown in Figure 1.

1. Function button (Offering four menu options; for more information, please refer to “10.1. The Push Button: Different Functions of the Device” section)
2. Command symbols,
3. LCD,
4. Air connector.

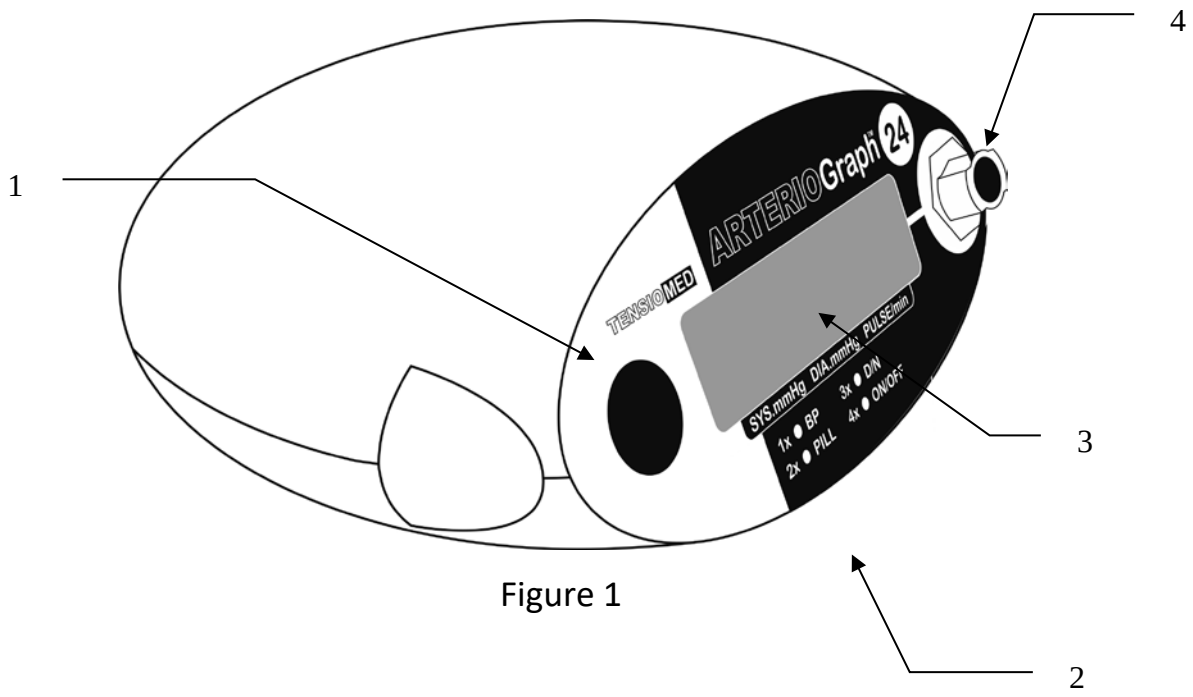


Figure 1

The symbols on the data label (bottom cover) of the device are shown on Figure 2.

5. Name of the Manufacturer and Year of Production
6. The name of the device
7. The type (version) ID of the device
8. The classification of the MDD requirements: IIa
9. The nominal voltage range applicable with batteries
10. The classification of the protection against electric shock
    Classification: patient's side: CF.
11. Calling attention to reading this instruction for use thoroughly
12. Certification Mark Guaranteeing Compliance with EU Requirements.
13. Serial number
14. Operating ambient temperature range
15. Address of the Manufacturer (TensioMed)
16. The discarded devices must be collected in order to get more efficient reuse and recycling, as well as harmful effects on human health and for the environment of the ingredients are selectively collected.

17. Level of protection against any liquid or grainy material filtering into the device (IP N_1N_2)
N_1=2: Protected against solid foreign objects of 12,5mm and greater
N_2=0: Not protected against water
18 Notified body ID number

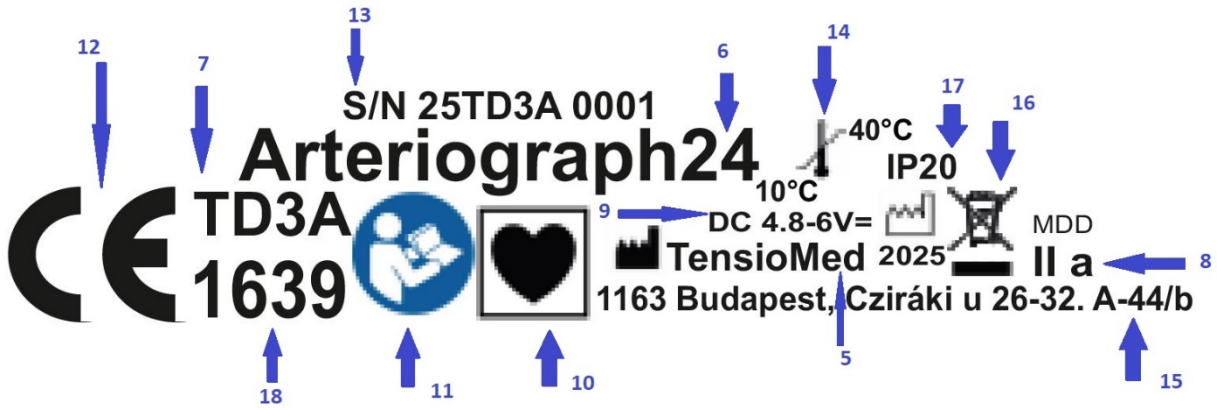


Figure 2

2.2. Accessories

The Arteriograph24 device (Figure 1), is supplied with the following accessories:

- Three cuffs of different sizes (see below)
- TensioWin software on a flash drive, along with instructions for use
- Instruction for use

The cuff is the Applied Part (AP) of the device that necessarily comes into physical contact with the patient during the intended use of the device to perform its function.

The cuff sizes are as follows:

Cuff type	Cuff dimensions	Arm circumference range
Cuff: **S**	42,5 × 10 cm	20 – 24 cm
Cuff: **M**	55 × 14 cm	24 – 32 cm
Cuff: **L**	65 x 14 cm	32 – 38 cm

The manufacturer of the cuffs:

Vistar Medical Supplies Co., Ltd.
8th Floor, Hanhaida Building, No. 7 Songgang Blvd.
Shenzhen, 518105 China

2.3. Preparing the device for operation

Battery Operation:

- The Arteriograph24 is powered by 4 AA alkaline batteries. Insert them carefully, ensuring the correct polarity (as shown in the user manual or device diagram).
- The device also includes a CR2032 battery that powers the clock circuit, ensuring time is maintained even when the AA batteries are replaced. No need to reset the time after changing the AA batteries. Each time a measurement protocol is transferred from the PC, the device clock will automatically update.

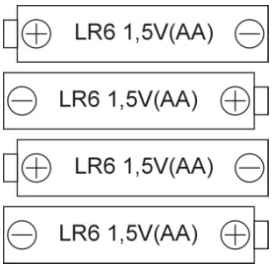


Figure 3

Battery Maintenance:

- If the device is not going to be used for more than 2 hours, it is recommended to remove the batteries and store them in a cool, dry place.
- Avoid exposing the batteries to heat, as this may cause an internal short circuit.
- Dispose of spent batteries immediately and in an environmentally responsible manner.

Bluetooth Connection:

- Your computer must have active Bluetooth capability to connect to the device.
- The Bluetooth icon will appear in the system tray on your PC, indicating that the Bluetooth service is active.
- If your computer does not have built-in Bluetooth functionality, you can use a Bluetooth dongle to establish the connection.
- The device must be within 5 meters (about 16 feet) of the computer for a successful Bluetooth connection using the TensioWin software.

2.4 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 flash drive into the USB port. The installation will start automatically. If it doesn't start, double-click the setup.exe file to begin the installation.

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. Introduction of TensioWin software

3.1 The structure of the TensioWin software

Account Selection:

- When starting the software, a login dialog window will appear.
- From the drop-down list, you can choose any previously registered login name associated with your account.

Default Login Name:

- If you don't have a custom login, you can select the default login name "Arteriogram."

Password Entry:

- Enter your password for the selected login account to gain access to the software.

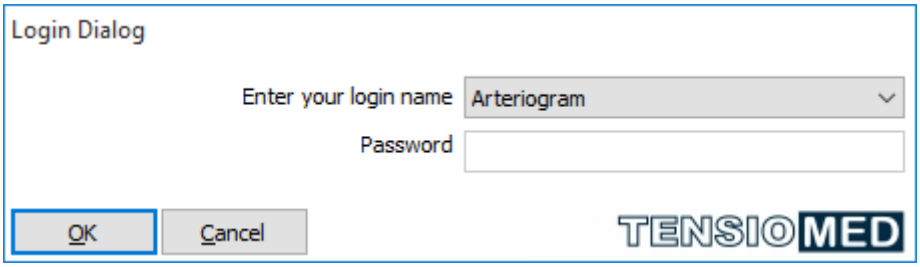


Figure 4 – Login

3.2 Overview of the TensioWin Control Panel

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

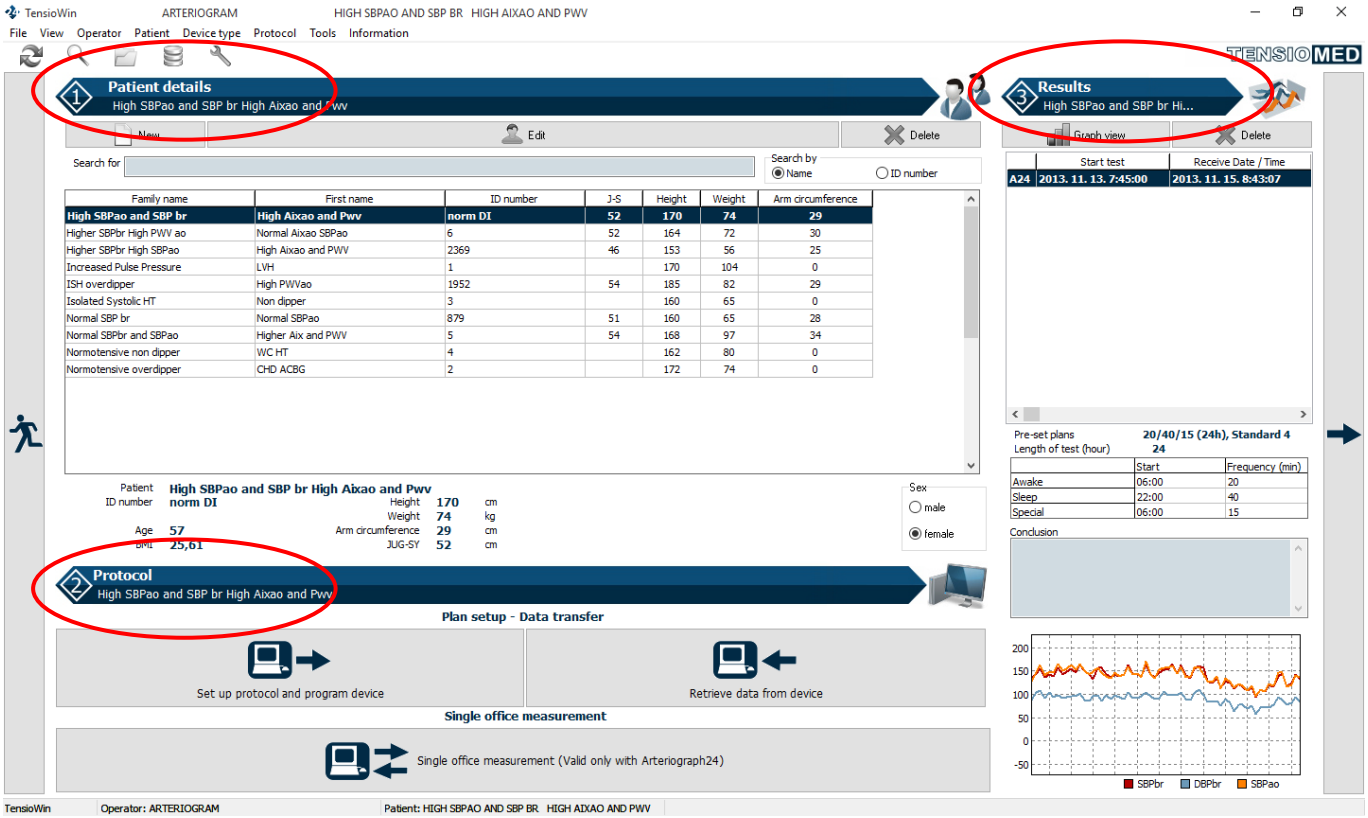


Figure 5 - Control panel

1. Patient details: The first module of the software displays key details of the currently selected patient and provides several functions for managing patient data. These functions include:

- View Patient Details:
    - Displays information about the currently selected patient.
- Add New Patient:
    - You can add a new patient's information into the system.
- Edit Patient Information:
    - Allows you to modify or update the details of an existing patient.
- Delete Patient Data:
    - Enables you to remove a patient's details from the system if needed.
- Search for Patients:
    - Provides a search function to easily find patients within the system based on their details.

This module helps you efficiently manage patient records within the software.

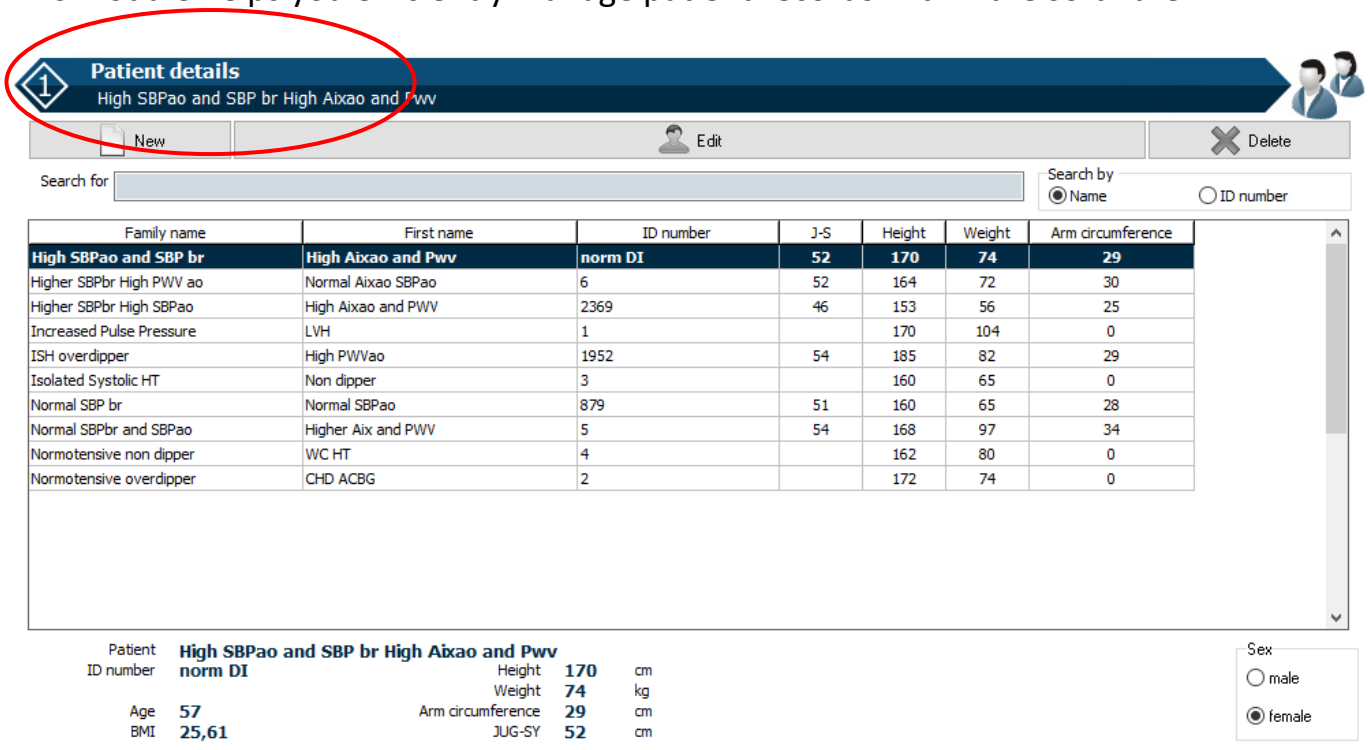


Figure 6 - Patient data

2. Protocol: The second module is designed to facilitate communication with the Arteriograph24 device. It allows you to perform the following functions:

- Programming the Device:
  - You can configure or program the settings of the device directly from the software, ensuring it is set up for your specific measurement needs.
- Downloading Measured Data:
  - This function allows you to transfer the data measured by the device back into the software for analysis, review, or further processing.

This module ensures smooth interaction between the software and the device, enabling real-time data exchange and device configuration.

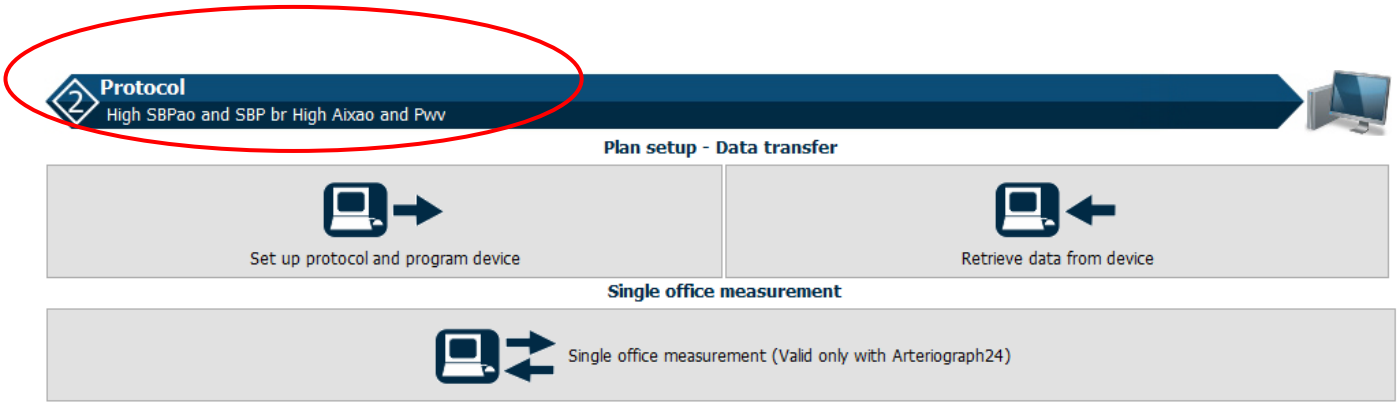


Figure 7 – Protocol

3. Results: The third module displays a list of all measurements for the currently selected patient, along with a preview of the selected measurement. You can navigate through and select a specific measurement using the following options:

3.1 Clicking on the Chosen Measurement and Selecting the “Graph View” Button:

- This opens a graphical representation of the selected measurement, allowing for a more detailed analysis.

3.2 Clicking on a Given Measurement and Selecting the “Continue” Button (Arrow on the Right):

- This option takes you to the next step in the workflow or further processing of the selected measurement.

3.3 Double-Clicking on the Measurement:

- Double-clicking on a measurement will immediately open it for viewing or editing, depending on the context.

These options provide flexibility in reviewing and managing the patient's measurement data efficiently.

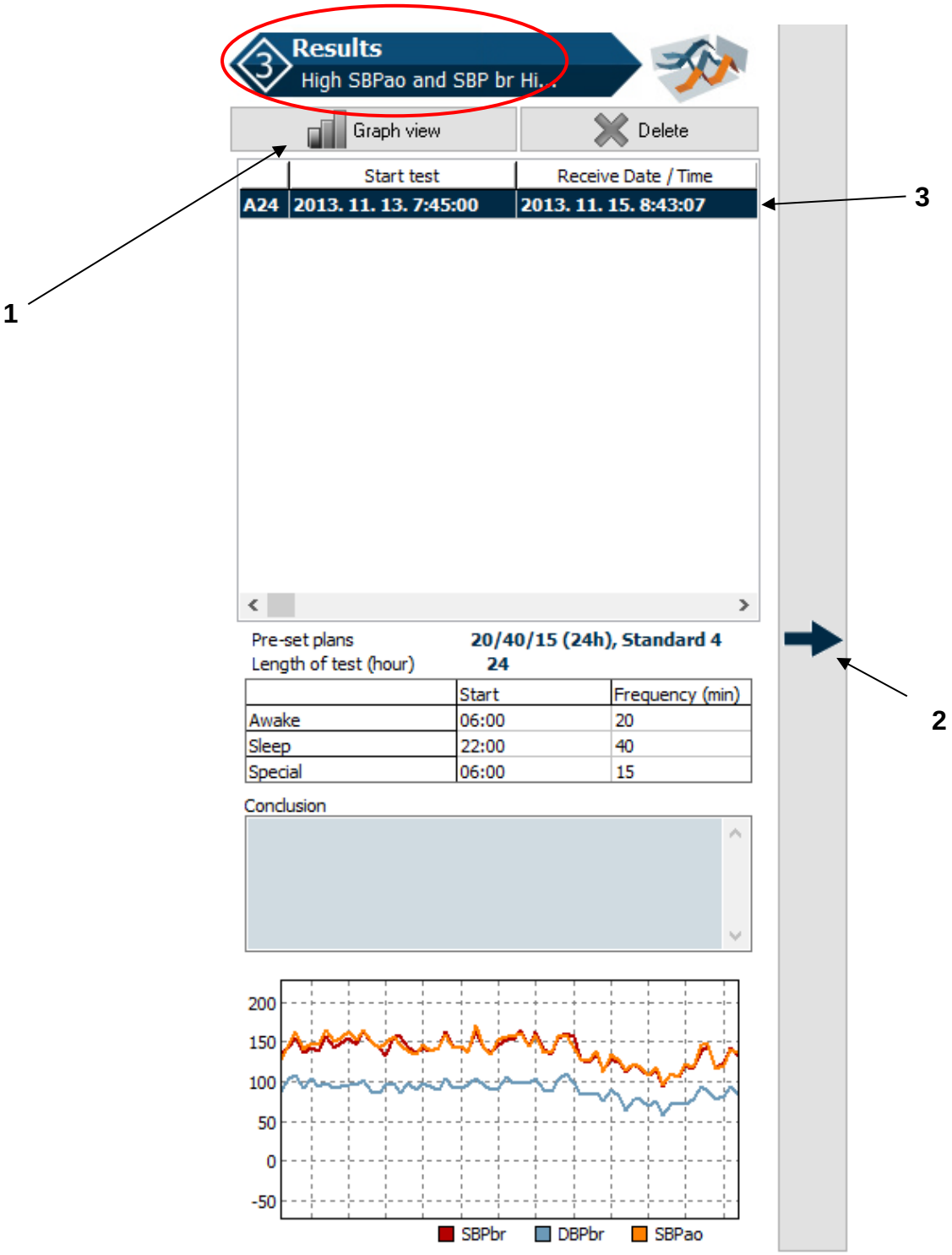


Figure 8 - Results

3.3 The menu bar of TensioWin

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

File

Import data file: 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.

Patient functions: 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.

Change Operator: Login to a user account.

New: A new account can be added by clicking on this option.

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

Delete: Data of a selected user can be deleted here.

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

Patient:

Add, edit or delete patient data.

New: 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:

- Arteriograph24 (24-hours Arteriograph)
- TensioDay Plus
- TensioDay

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® devices during the monitoring period and display it.

Single office measurement:

This function works only for Arteriograph24 devices which were produced from 2017.

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 initial pressure of the device to:
  - an arbitrary value
  - 50 mmHg above the previous MAP value
- examination of the cuff inflation,
- you can download the actual date and time into the device,

The above-mentioned settings only take effect after sending those to the device by pressing the “Download into the device” button.

1. Select the type of the device.
2. 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

User’s manual: 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 a New Operator/Physician
  1. Go to the "Operator/New" Tab:
     - In the software, click on the "Operator" tab and select "New".
  2. Enter the New Operator's Info:
     - A pop-up will appear where you can enter the operator's details.
     - Fill in all required fields (marked in color). These fields are mandatory.
  3. Save the New Operator:
     - Once you've added the information, click OK to save.
     - The new operator will show up in the login list when you start the software.
- Switch Between Operators
  1. Change Operator:
     - If you want to log in as a different operator, click on “Change Operator” in the main menu.
  2. Select the Operator:
     - A list will appear with all saved operators. Choose the one you want by clicking on their name and pressing OK.
- Edit Operator Info
  1. Modify Operator Details:
     - To update an operator's information, go to the "Operator/Edit" tab, select the operator, and change the details.
  2. Save Changes:
     - Click OK to save any edits.
- Delete an Operator
  1. Delete an Operator:
     - To remove an operator, go to the "Delete" option.
     - You can delete one or more operators at a time.
  2. Enter Password:
  - To confirm, you’ll need to enter the operator's password to complete the deletion.
  3. Restart Software:
  - After deleting the operator, restart the software for the changes to take effect.

These options help you easily manage user access to the TensioWin software by adding, editing, switching, or removing operators as needed.

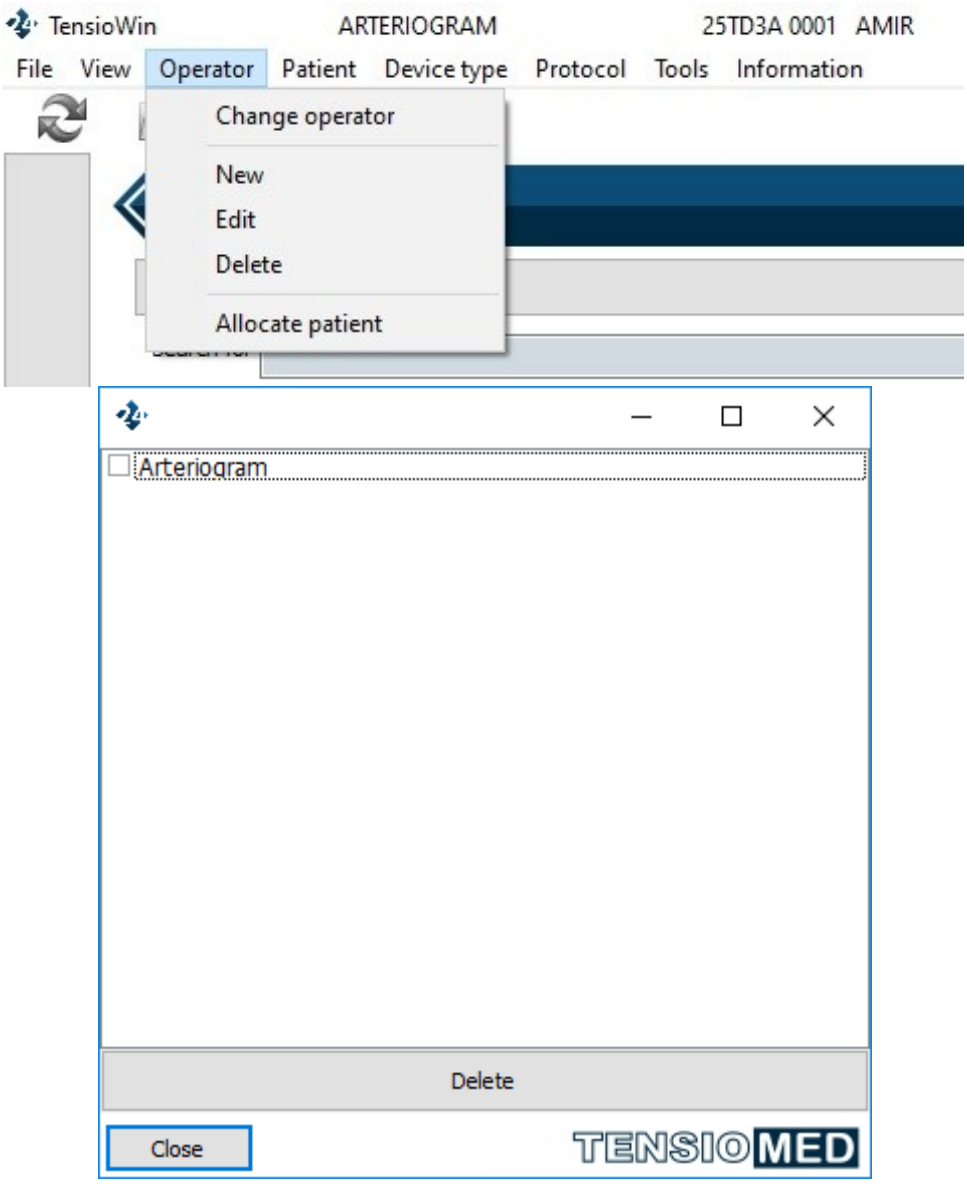


Figure 9 - Operator Setting

Allocate Patient

If you want to assign an existing patient to a different operator:

1. Use the Allocation Function:

Select the “Allocate patient” function in the software.

2. Enter the Operator’s Password:

A pop-up window will appear. To allocate the patient, you will need to know the password of the current operator who is assigned to the patient.

3. Select the Patient(s):

Choose the patient(s) you want to allocate to another operator from the list.

4. Allocate the Patient:

After selecting the patient(s), click the “Allocate patient” button to complete the process.

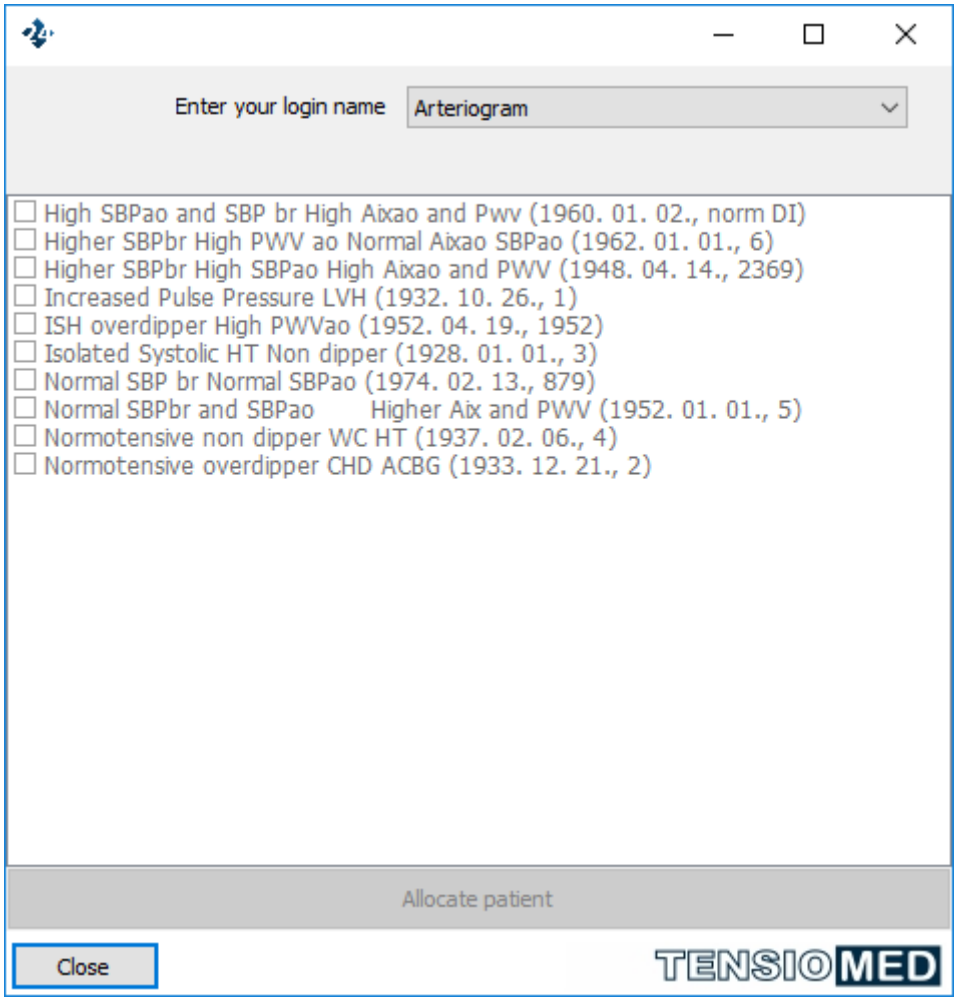


Figure 10 - Allocate patient

4.2 Patient's data

Selection of the patient

To select a patient in the software:

- Use the "Patient details" module:
  - Simply click on the patient's name listed in the module.
- Search for a patient:
  - If you can't find the patient easily, use the “Search for” function.
  - You can search by name or ID number.

Note: Toggle the search setting on the right side of the search bar to choose whether you want to search by name or ID.

This allows you to quickly find and select any patient within the software.

Add a new patient

To add a new patient:

Click “New” in the “Patient details” module or go to the “Patient - New” menu item.

A pop-up window will appear where you can enter the patient’s details.

the following highlighted fields must always be filled:

- ID number
- Family name
- First name
- JUG-SY distance (distance between the suprasternal notch and the pubic bone)

Note: If the Auto JUG-SY function is activated, the system will automatically calculate the JUG-SY value based on the height you provide.

- Arm circumference
- Height

After entering arm circumference, the software will suggest the appropriate cuff size to be used.

The form follows the typical steps of an outpatient visit as well, and you can enter information about:

- Referring diagnosis
- Medical history
- Laboratory data
- Cardiovascular risk assessment (optional),

Note: Any comments or opinions you enter will automatically be included in the patient’s printed report.

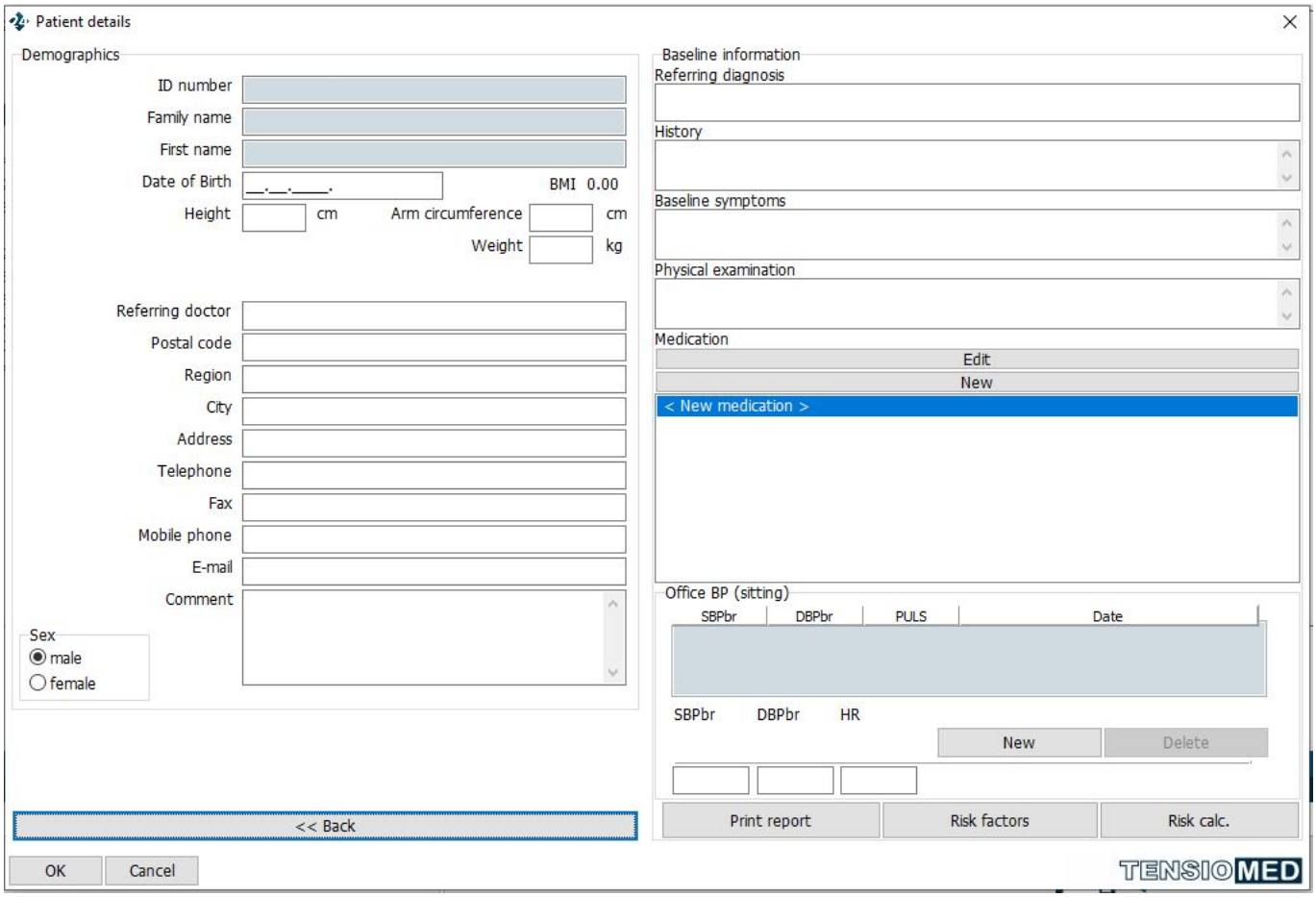


Figure 11 - Patient details

To measure the JUG-SY distance:

- Use the supplied tape measure.
- Place one end of the tape at the suprasternal notch (the dip at the top of the chest).
- Measure down to the pubic bone.
- Once you have completed the details, you can save the data by clicking “OK”.

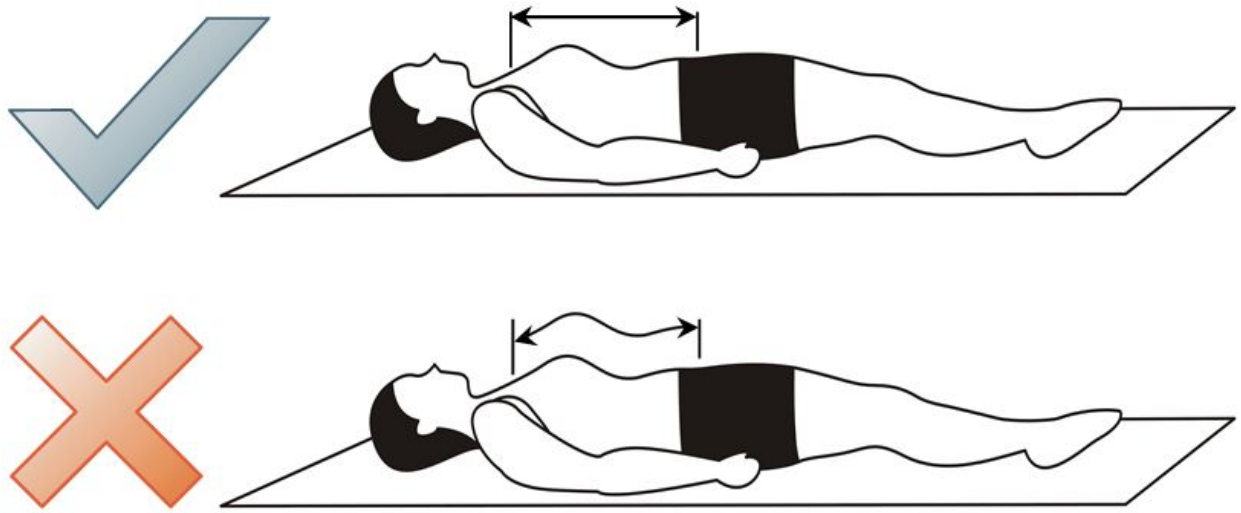


Figure 12 - JUG-SY Measurement

Please note: Measuring on the body surface might lead to overestimations, especially in obese patients, so it’s important to measure in a straight line from the suprasternal notch to the pubic bone.

Edit patient data

If the patient returns for a follow-up visit or has new laboratory or blood pressure data, you can easily update their information and prepare a follow-up report. Here's how to do it:

- Select the Patient: In the “Patient details” module, choose the patient whose data you want to update.
- Click the "Edit" Button: You can either click the “Edit” button directly or go to the “Patient/Edit” menu option.
- Edit Patient Details: A pop-up window will appear, allowing you to modify the patient’s information.
- Automatically Updated Fields: In fields like “Baseline symptoms,” “Physical examination,” and “Office blood pressure,” the current date will automatically appear. You can also review previous data by using the scroll bar.
- Save Modified Data: Only the data entered with the latest date will be included in the printed report. Once you’ve made your changes, click “OK” to save the updates.

This process ensures that the patient’s most recent information is used for follow-up visits and reports.

Enter and delete office blood pressure data

To enter new office blood pressure measurements for a specific patient, follow these steps:

- Select the Patient: In the “Patient details” window, choose the patient whose office measurements you want to update.
- Click “Edit”: After selecting the patient, click on the “Edit” button.
- Click “Next”: In the pop-up window, click the “Next” button to proceed.
- Enter the Measurements: Input the systolic and diastolic blood pressure readings and also the heart rate value.
- Click “Save”: After entering the values, click “Save.” The measurements will be listed in the right panel with the corresponding date and time.

Repeat for Additional Readings: If you have more office blood pressure readings to enter, repeat the steps for each new reading.

View Average: The average of the readings from the same date is automatically calculated and displayed at the bottom of the panel. This average can be printed as well.

Deleting Previous Office Blood Pressure Data:

- Select the Data to Delete: Click on the row of data you want to delete. The selected data will appear on the left side of the Office BP panel.
- Click “Delete”: Once the data is selected, click the “Delete” button to remove it.

These steps allow you to efficiently manage the patient's office blood pressure readings, including entering new measurements and deleting outdated ones

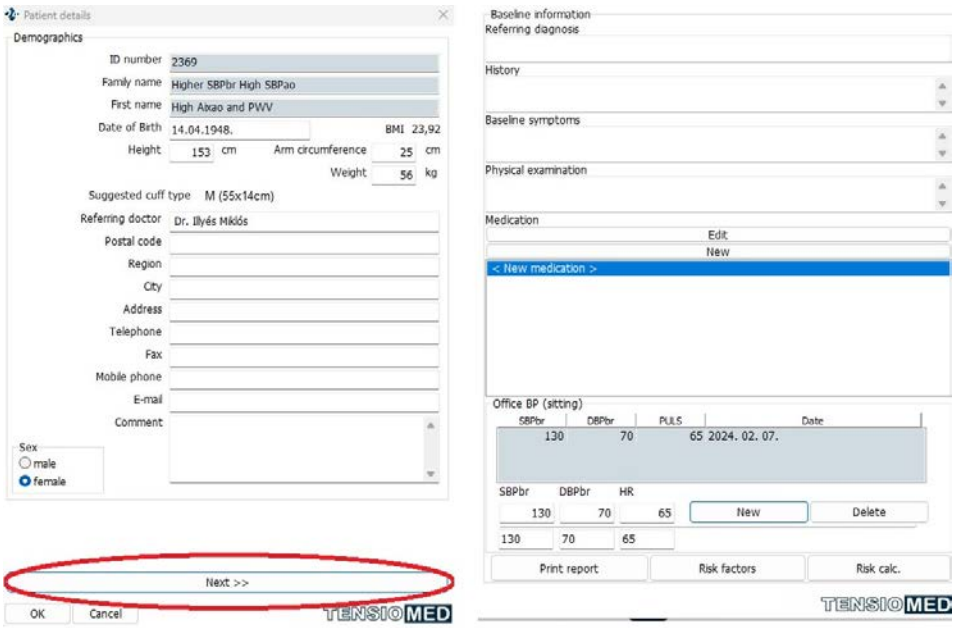


Figure 13 - Entering office blood pressure data

Assessing cardiovascular risk factors

To assess the risk of cardiovascular events over the next 10 years based on the Framingham Risk Score, follow these steps:

1. Enter Risk Factor Information:
    - Go to the “Risk factor” page in the patient details window.
    - Input all the necessary information related to the patient's risk factors for cardiovascular disease.

To calculate the cardiovascular risk, ensure the following data is entered for the patient:

- ✓ Date of birth
- ✓ Sex
- ✓ Systolic blood pressure
- ✓ Current smoking status
- ✓ Diabetes status
- ✓ Left ventricular hypertrophy (detected by ECG)
- ✓ Cholesterol and HDL-cholesterol values

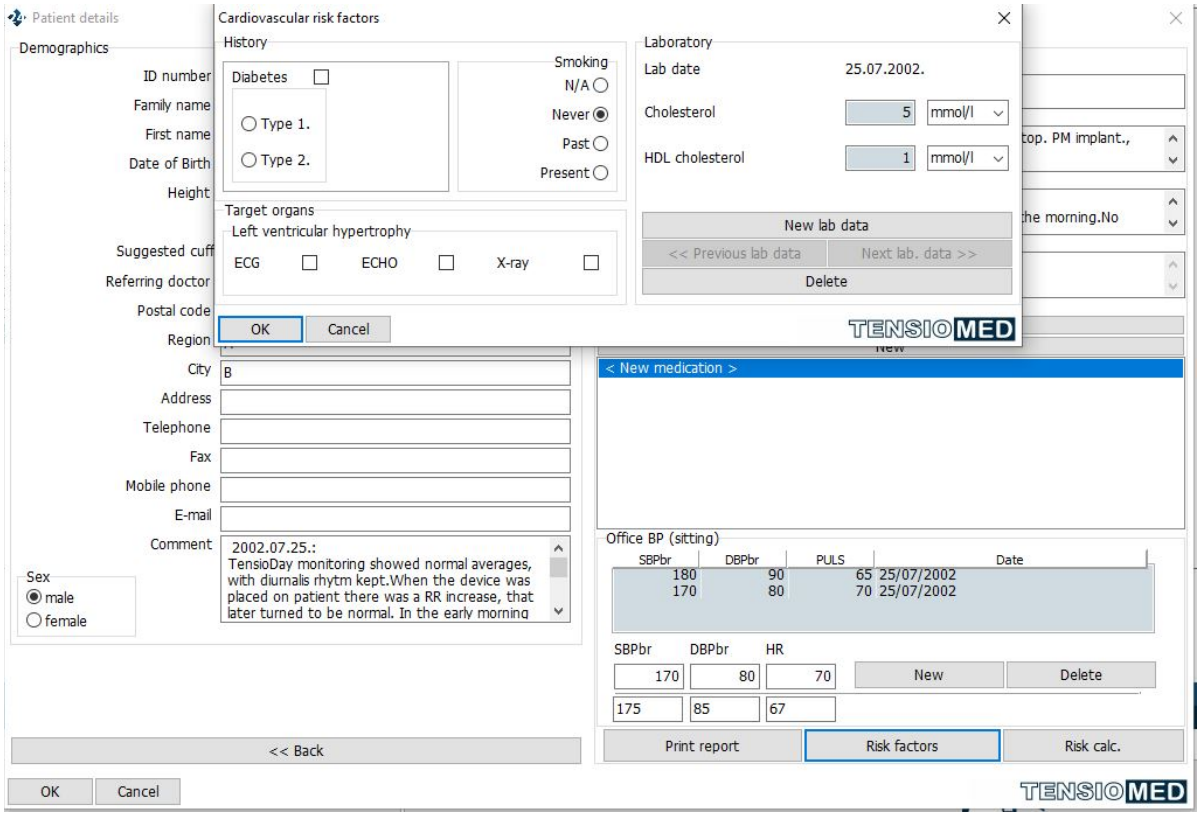


Figure 14 - Cardiovascular risk input

2. Calculate Risk:
    - After entering the required information, click the “Risk Cal.” button to calculate the patient's cardiovascular risk.

Note: The risk is calculated using the equation from the Framingham Heart Study (Anderson KM et al. Cardiovascular disease risk profiles. Am Heart J 1990;121:293-8).

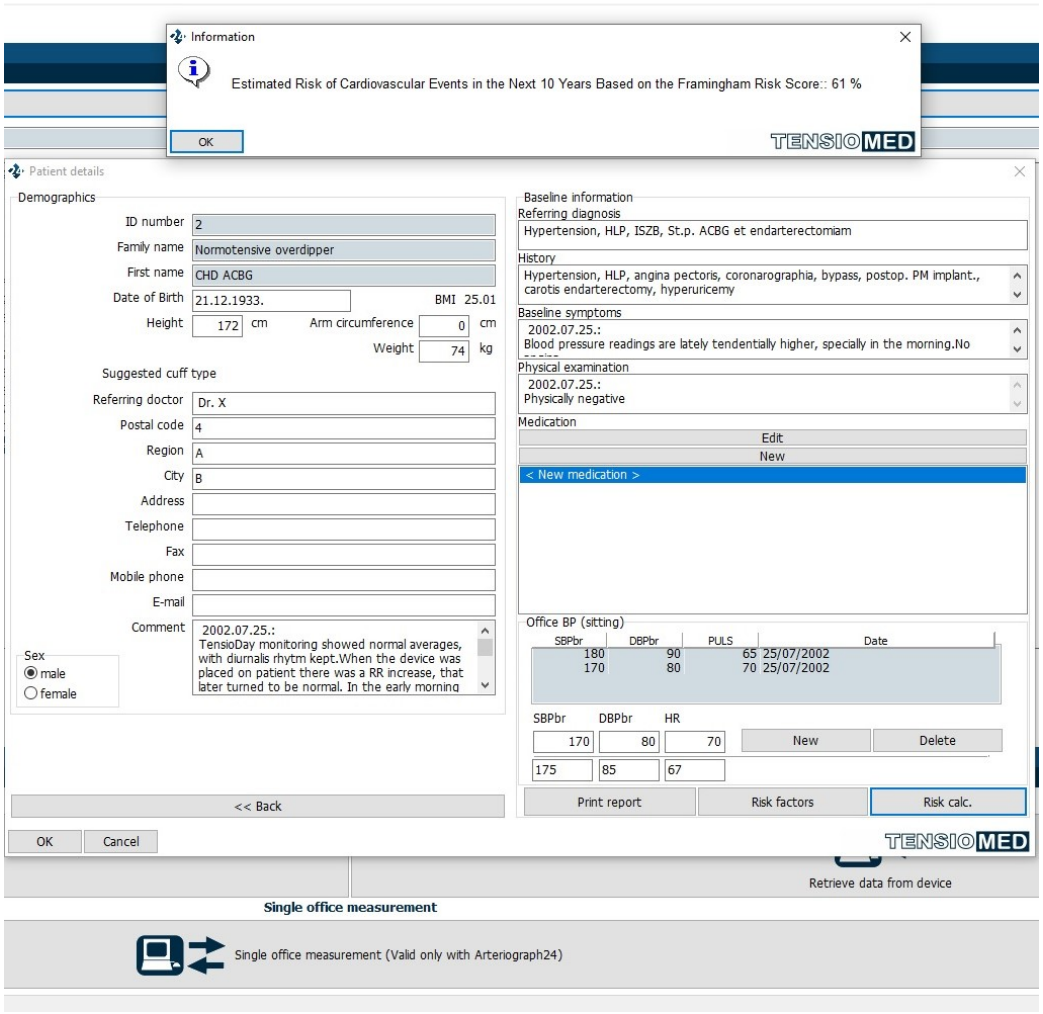


Figure 15 - Calculation of cardiovascular events

Entering and Deleting Laboratory Data:

To manage laboratory data in the Cardiovascular Risk Factors window:

- Adding New Laboratory Data:
  - Click “New lab data”: In the laboratory data panel, click the “New lab data” button to add new data.
  - Choose Unit of Measurement: Select the unit of measure (e.g., mmol/l or mg/dl) for the laboratory values.
  - Fill in the Details: Enter the laboratory data in the available fields.
  - Save the Data: Click “Save” to store the entered data. The current date will be automatically added to the panel.
- Viewing Previous Laboratory Data:
  - To view any previously entered laboratory data, click on the “Previous lab data” button.

- Deleting Laboratory Data:
    - Navigate to the Data: Use the “Previous” or “Next” buttons to locate the laboratory data you want to delete.
    - Click “Delete”: Once you find the data, click the “Delete” button to remove the data for that date.

By following these steps, you can assess the cardiovascular risk of your patients and manage their laboratory data effectively.

5. Programming the device

To ensure accurate and efficient measurement, it’s important to configure the device with the correct protocol before starting the patient’s assessment. Follow these steps to set up the measurement protocol and program the device:

- Access the Protocol Setup:
    - Navigate to the Protocol module and find the "Plan setup – Data transfer" section.

- Configure the Protocol:
    - Click the “Set up protocol and Program device” button to initiate the process of configuring the measurement settings and programming the device accordingly.

This will enable you to customize the device to the required settings, ensuring that all measurements are conducted under the correct parameters for your patient’s needs.

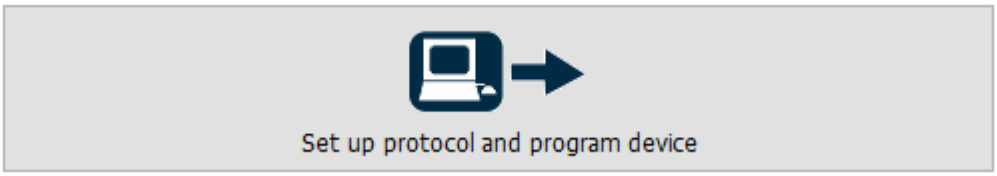


Figure 16 - Programming the device

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

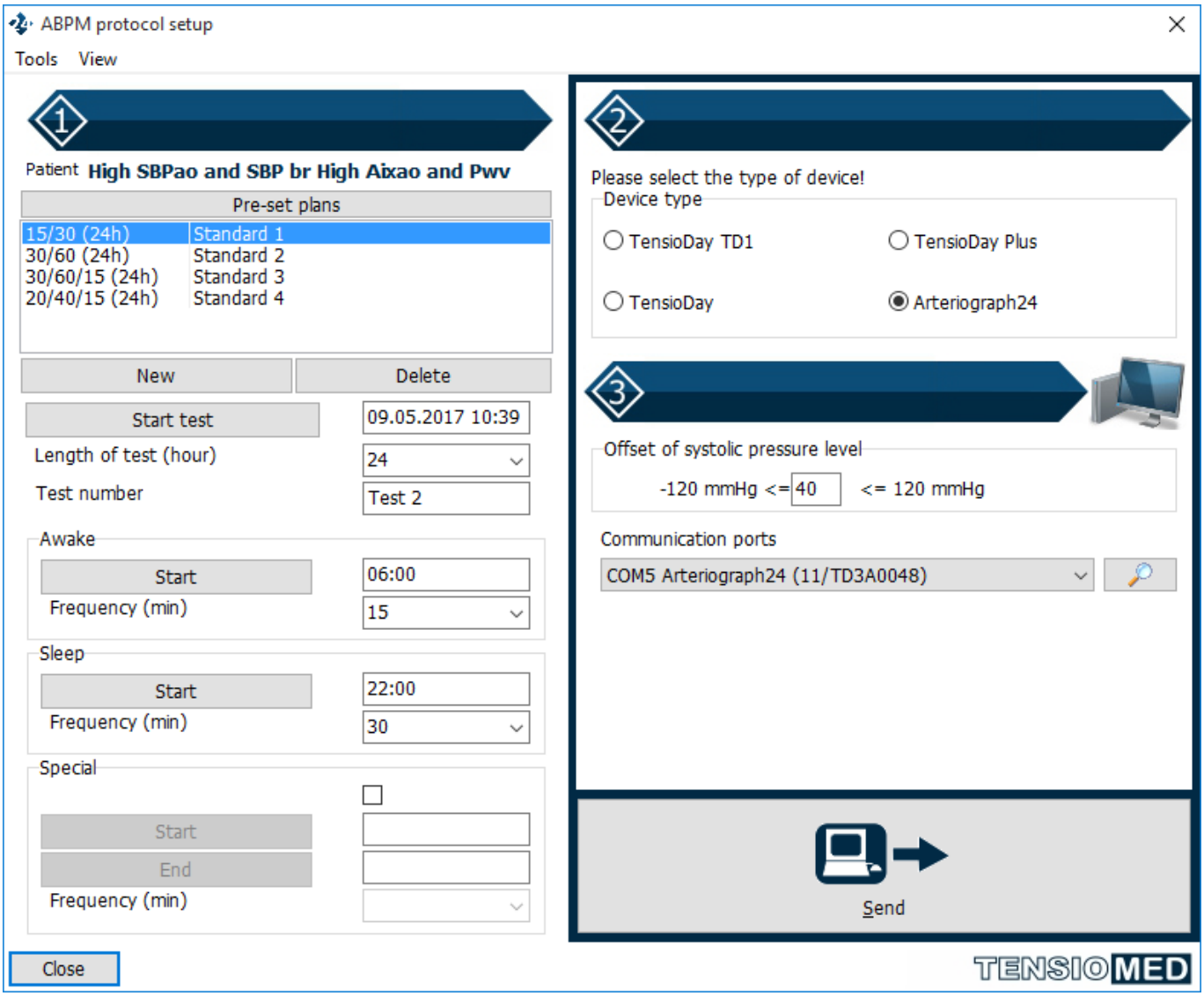


Figure 17 - Measurement protocol

Pre-set plans are listed in the window. The first number in the plan's name shows the measurement frequency during the active period, the second number shows the frequency during the passive period, and the third number shows the frequency during the special period (e.g., 30/60/15). The length of the planned monitoring is shown in parentheses (e.g., 24h).

Even when you select a pre-set plan, you can adjust:

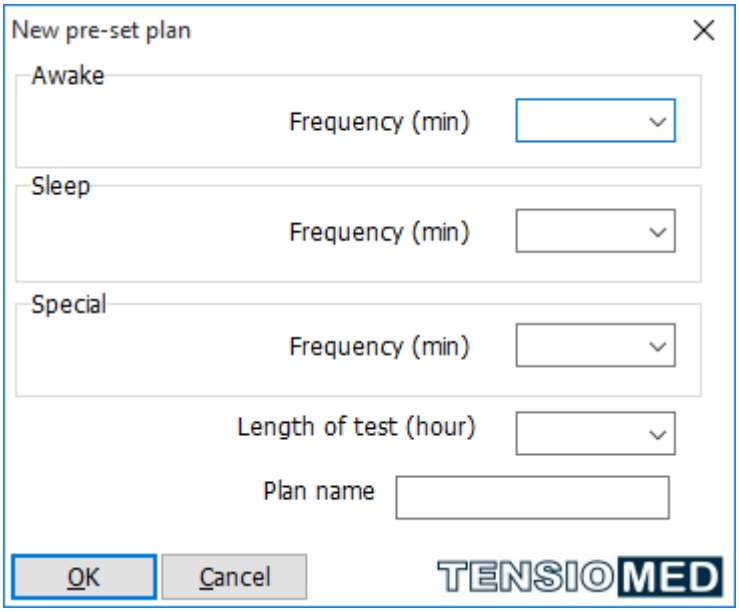
- The length of the test
- The start time of the test
- The different periods

- The measurement frequencies for each period

You can program measurements for up to 72 hours with frequencies ranging from 10 to 90 minutes.

If you need to use different monitoring schedules often, click "New" to create custom protocols. This lets you define a new plan with specific test length and measurement frequencies for the "active" day period, "passive" night period, and any additional "special" period.

To save the new pre-set plan, click OK after naming it. The details of the new plan will then appear in the window.



12. Protocol setup

You can always modify the starting time of the test.

Once the protocol is set, click on the “Send” button.

Since previous TensioMed® products, such as TensioDay and TensioDay Plus, can also be managed by the TensioWin software, you must select the correct device type when starting data transmission.

If the communication port is unknown, you can select the desired port (device) from the drop-down list. The software also has an automatic port selection feature that detects the currently connected active device and connects it to the PC.

Warning! Before starting the communication, make sure the clock is displayed on the screen. Ensure that you do not see "BLUELINK" or "CONNECT".

If multiple devices are available but only one needs to be used, manually select the device and port from the drop-down list. This will prevent automatic searches and stop other devices connected to different ports from being re-programmed.

- Click "Send" to begin.
- "CONNECT" will appear on the device screen, and the successful download will be confirmed.

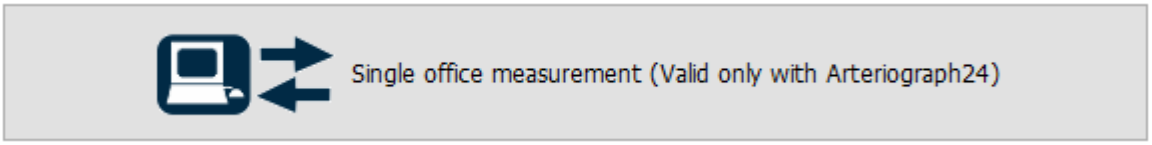
You can track the progress of downloading the measurement protocol on the progress bar.

To remove previously registered devices from your list, go to "Tools" in the "Set up protocol and program device" window and select "Delete the previously registered devices."

5.1. Single office measurement

From the TensioWin program it is possible to start a single Arteriograph measurement without 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

After the patient data is approved, a communication port selection window will appear.

To start the measurement, click the "Start" button.

During the measurement, a communication window will show while the Arteriograph24 performs the test and sends the data to the TensioWin software. Once the results are ready, they will be displayed in the report.

6. Retrieve data from the device

To transfer data from the Arteriograph24 to your computer, follow these steps:

- Select the Patient: Choose the correct patient from the list.

- Retrieve Data: In the "Plan setup – Data transfer" section, click the “Retrieve data from device” button.

This will allow the data collected by the Arteriograph24 to be transferred to your computer for further analysis and record-keeping.

Figure 18 - Retrieve data

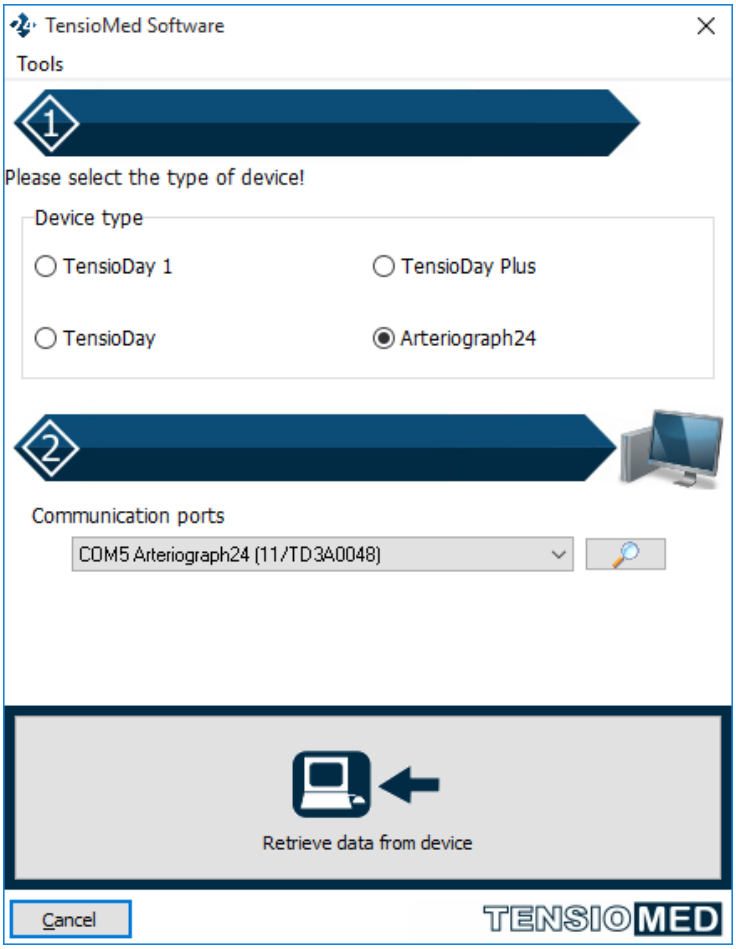


Figure 19 - Retrieving data & selecting the device and the communication port

Now, follow these steps:

1. Device and Port Selection: Once you click to retrieve data, a pop-up window will appear where you need to select the correct device and port. Since previous TensioMed® products like TensioDay and TensioDay Plus are also managed by the TensioWin software, make sure to choose the right device type for proper data transfer.
2. Download Measurements: In the new window (TensioMed software), from the drop-down list under the “Tools” menu, select “Download measurements of current patient to the PC”.
3. Notification: If the device was programmed on a different computer than the one currently running the TensioWin software, you will see a notification. To ensure consistency, always use the same computer with the device.

4. Patient Selection: Confirm that the correct patient is selected before transferring the data, ensuring it matches the one the measurement was taken for.

Note: You can transfer the blood pressure data anytime during the measurement. This is helpful for checking the device's performance or viewing the blood pressure values while the measurement is still ongoing. Transferring data during the process will not interrupt the set protocol, and the examination will continue until the set length is completed.

Note: If you transfer data before the measurement is complete, this will be reflected in the “Status” window of the first page of the Analysis section. Any additional data transferred at the end of the monitoring will be appended to the previously transferred partial results for a comprehensive data analysis.

This ensures smooth data transfer without affecting ongoing examinations.

6.1. Data transmission

The device transfers all the stored data to the physician's PC via Bluetooth communication. The information loaded consists of:

- the brachial systolic and diastolic blood pressure values (mmHg)
- the heart rate per minute
- the arterial function parameters (central SBP, PP, brachial and aortic Aix, aortic PWV)
- the distinction between programmed and manual measurements
- the date and time of the measurement
- the active or passive period
- the diary of medication intake.

If a Bluetooth communication is placed within the range of the device and the connection is successful, this sign will appear on the LCD. The actual data transmission does not happen yet. This can be started using the TensioWin program.

BLUELINK

During the operation of the Bluetooth communication between the device and the PC, when the actual data transmission is in process, the following sign will appear on the LCD. When the data transfer is finished, the sign is removed from the LCD.

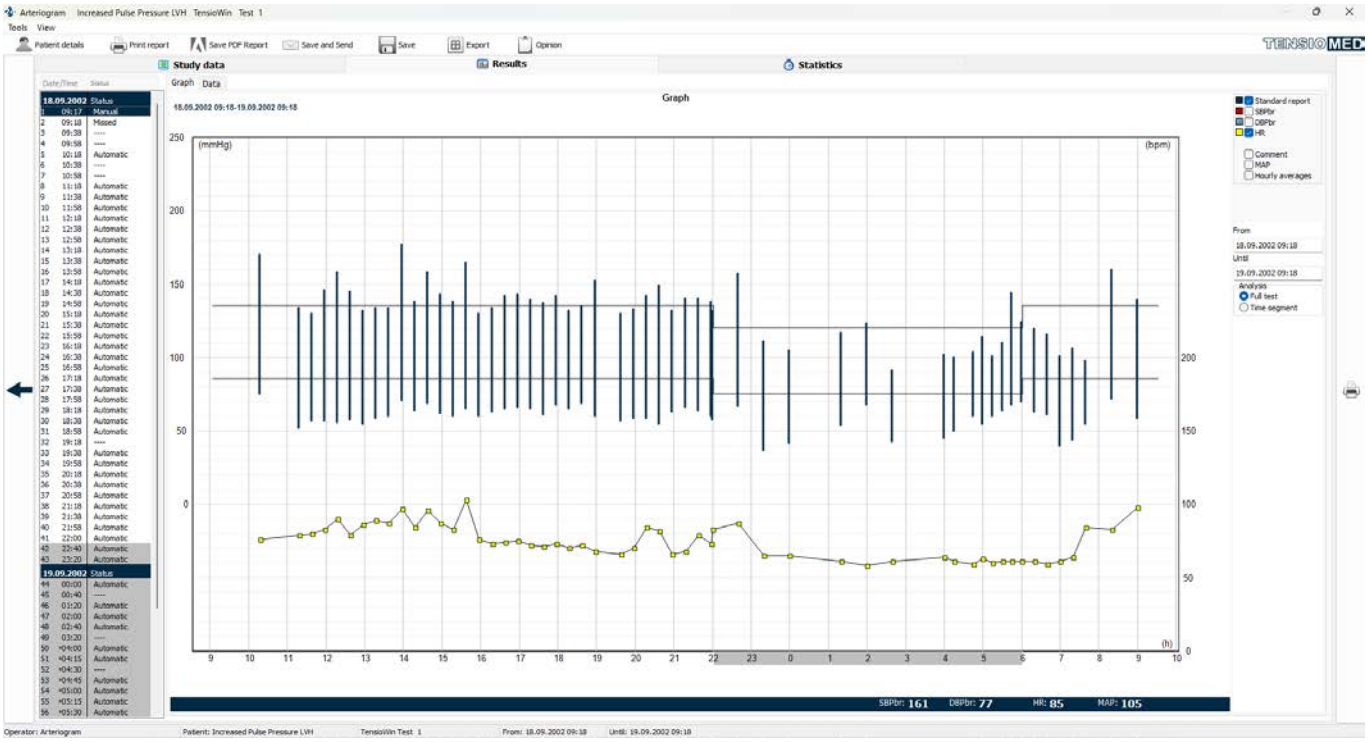
CONNECT

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.

4. **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”.

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.

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:

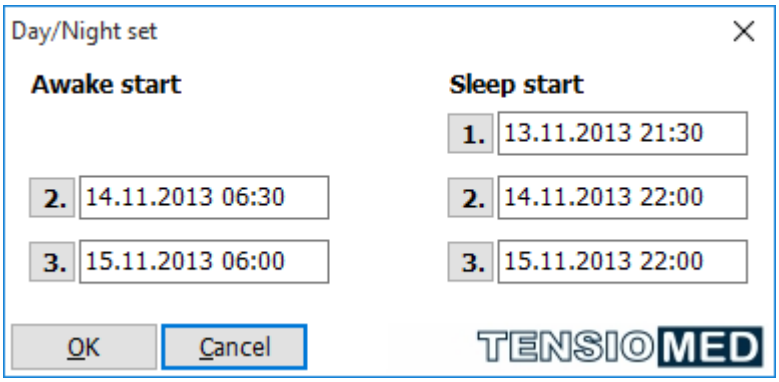


Figure 20 - Setting Day/Night

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.

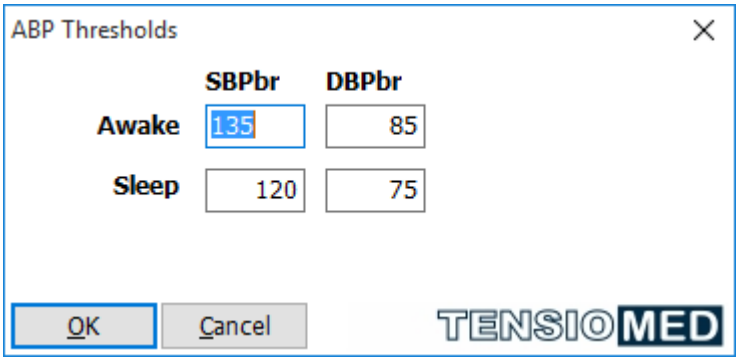


Figure 21 - Setting the thresholds

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

7.2 The Results window

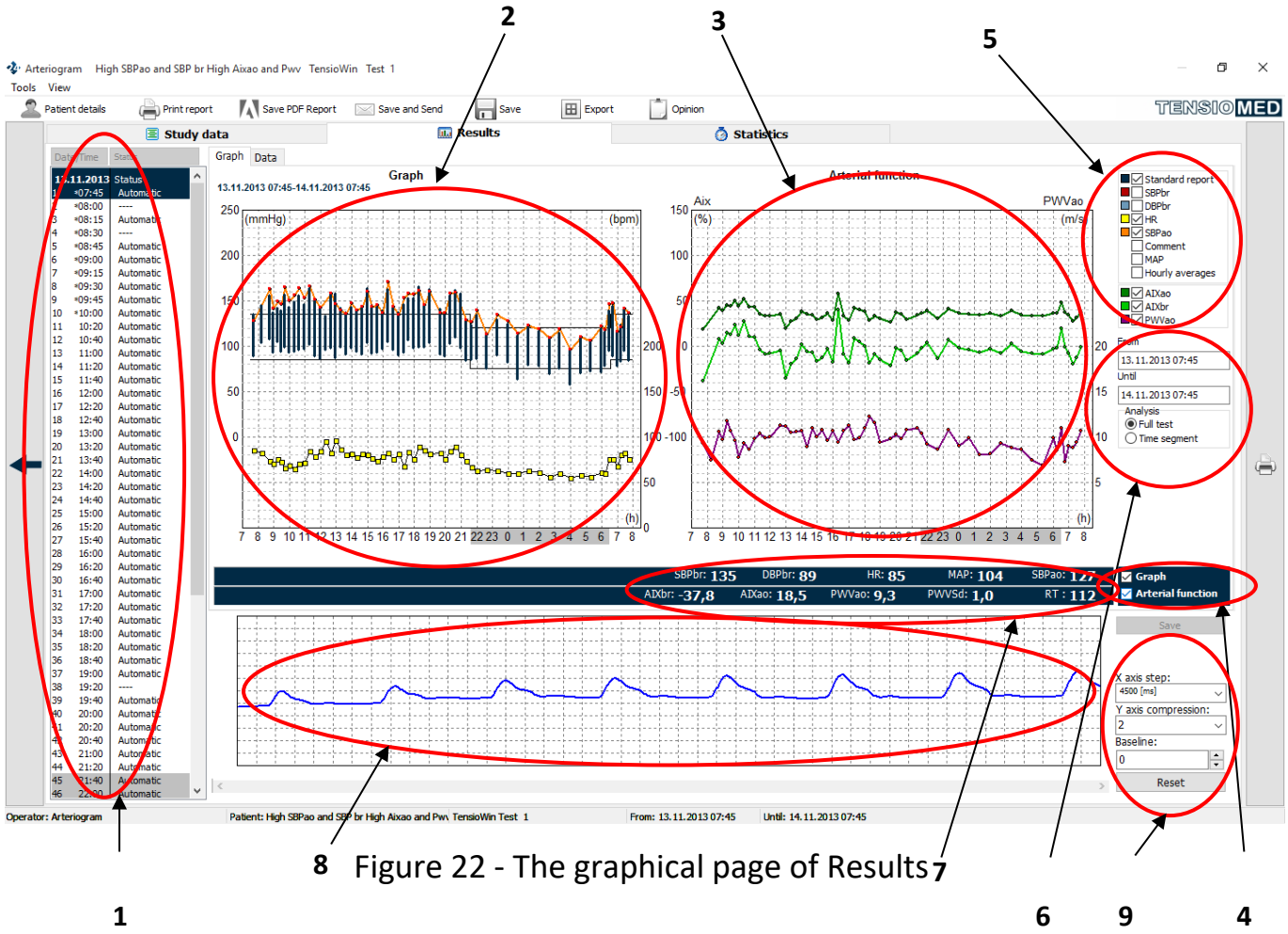


Figure 22 - The graphical page of Results

Two separate pages are available:

7.2.1. The Graph page

The signs of Figure 22. are as follows:

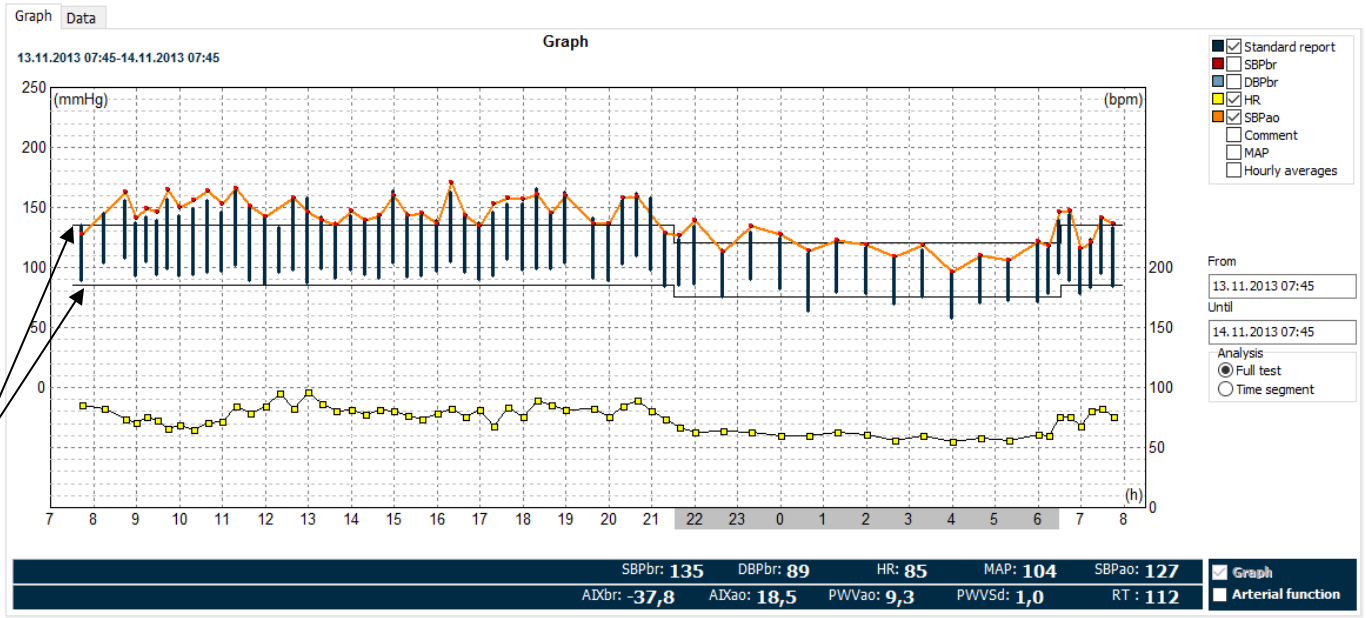
1. Standard measurement list
2. Blood pressure histogram
3. Arterial function histogram
4. Blood pressure histogram/Arterial function histogram display/hide
5. Select the displayed parameters
6. Select the displayed period
7. Numerical parameter values
8. Pulse wave curve
9. Display settings

Standard measurement list (1)

The measurement list facilitates a better connection between the measurements of a given patient. When you select a measurement:

- Red lines indicate the corresponding sections on the Arterial Function Histogram (3) and the Blood Pressure Histogram (2).
- The parameter values for the selected measurement are displayed in the Numerical Parameter Values section (7).
- The related pulse wave curve appears on the Pulse Wave Curve (8) display.

Blood pressure histogram (2)



10

Figure 23 - Blood pressure histogram

The graphical display of measurement data provides a clear visual representation of results. Key elements include:

Threshold Values: Solid black lines indicate the set thresholds for systolic and diastolic blood pressures during active and passive periods.

Note: You can modify the threshold values, as well as the start and end times for active and passive periods, on the "Study Data" page.

Pill Intake: Pill intake is marked with a green dot at the top of the graph.

You can adjust the graph display to suit your preferences:

- Histogram Display: Choose between discrete values or a continuous curve

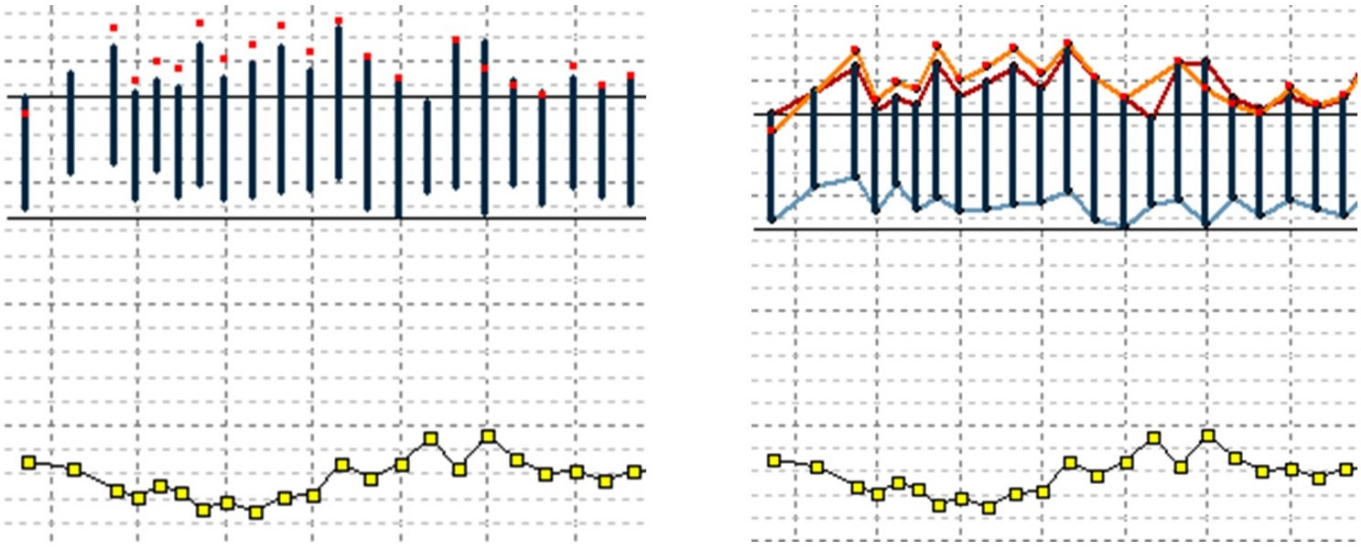


Figure 24 - Without connection or connected by a solid line

12. Comments Display: Show or hide comments entered on the second page.

13. Mean Arterial Pressure (MAP): Toggle the display of MAP.

14. Measurement View: Switch between individual measurements and hourly averages.

Time Segments: View either the full test period or a specific time segment.

To define a time segment, click "Time Segment" at the bottom of the page.

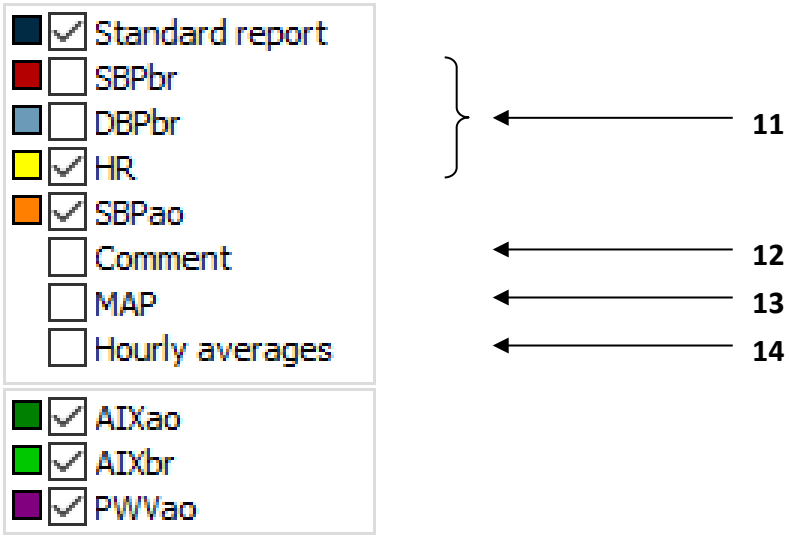


Figure 25 - Editing the graphical display

Arterial function histogram (3)

The graphical display of the arterial function parameters is shown on this graph. Similar to the Blood Pressure Histogram, the active and passive periods can be adjusted on the Study Data page. This allows for fine-tuning of the measurement periods to better analyse the arterial function.

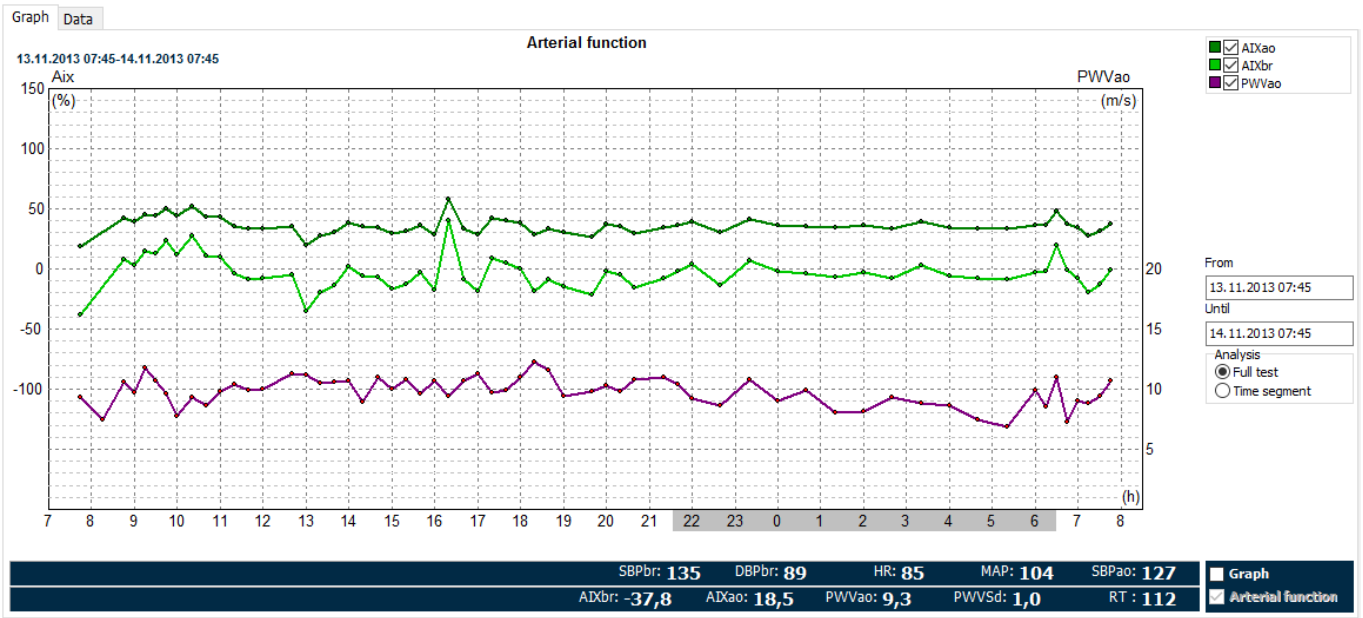


Figure 26 - Arterial function histogram

You can choose to display or hide the following arterial function parameters on the graph:

- AIXao (Aortic Augmentation Index)
- AIXbr (Brachial Augmentation Index)
- PWVao (Aortic Pulse Wave Velocity)

This flexibility allows you to evaluate arterial function parameters alongside other measured data either together or separately.

How to adjust the display? Simply use the checkboxes above the graph:

- "Graph" to toggle the measurement data.
- "Arterial Function" to toggle the arterial function parameters.

Pulse wave curve (8)

The Arteriograph24 device automatically records pulse wave curves for each measurement. You can select and analyse these curves easily using the Standard Measurement List:

- Selecting a Pulse Wave Curve:
  1. Open the Standard Measurement List (1).
  2. Choose the desired pulse wave curve from the list.
- Automatic vs. Manual Evaluation:

  By default, the software automatically analyses the selected curve.

- To perform a manual evaluation:
  1. Click on the starting point of the desired section of the curve.
  2. Hold the mouse button down and drag to select the required section.
  3. Release the button to complete the selection.
- Reviewing and Saving Results:
  1. If successful, the TensioWin software will analyse the selected section and display the numerical results above the curve (7).
  2. To save this manual evaluation as the final result, click the "Save" button.

7.2.2. The Data window

The Data Window displays a tabulated list of measurement details, including:

- Time and Date: When the measurements were taken.
- Measurement Data: Blood pressure, pulse wave, and other results.

Key Features:

1. Active, Passive and Special Periods:
   - Active periods are not highlighted.
   - Passive periods are shaded for easy identification.
   - Special periods are marked with an asterisk (*) at the beginning of the row.
2. Status Column:
   - Indicates whether the reading is from an automated or manual measurement.
   - Lists additional events like pill intake times and wake/sleep times.
3. Comment Column:
   - Add comments to a specific reading (e.g., "dizziness noted by the patient") by double-clicking the Comment section of the corresponding row.

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	

Figure 27 - Data window

Managing Readings:

1. Automatic Data Filtering:
   - The device automatically excludes extreme blood pressure and heart rate values during measurement.
   - However, summary statistics include all data shown in this window.
2. Manually Deactivating Readings:
   - To deactivate a specific reading:
     - ✓ Double-click the row.
     - ✓ Select the checkbox to make the parameters inactive (temporarily deletes the data).

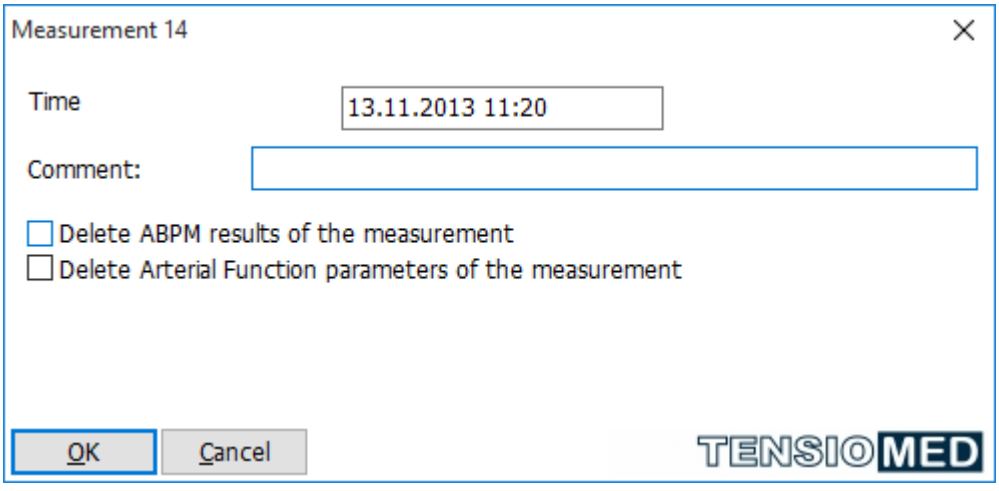


Figure 28 - Editing data

3. Deactivating Arterial Function Parameters Only:
    - For Arteriograph24, you can deactivate just the Arterial Function Parameters of a specific measurement by selecting the "Delete Arterial Function Parameters" option.

After deactivating the arterial function parameters, the brachial blood pressure curves 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.

7.3 Statistics window

The Statistics Window includes three tabs to help analyse and summarize test data:

I. Statistics Tab

This tab provides a summary of the test data, allowing you to define the periods to analyse (active, passive, or special) and whether to include the full test or a specific time segment.

Key Features:

- ✓ The start and end points for different periods can be redefined at any time.
- ✓ Temporarily deactivated values from the “Study Data” page are excluded from the statistics.

Statistical Summary Includes:

- ✓ Mean
- ✓ Maximum and Minimum Values
- ✓ Standard Deviation
- ✓ Diurnal Index (DI):
    - o Represents the percentage difference in mean blood pressure between the active and passive periods relative to the mean during the active period.
    - o Automatically updates if the active and passive periods are redefined.
- ✓ Percent Time Elevation (PTE):
    - o The percentage of time during the test when blood pressure exceeded the threshold limits.
    - o Assumes that the change in blood pressure between two readings is linear.
    - o Adjusts if the threshold values are changed by operator.
- ✓ Blood Pressure Load (Load):
    - o Represents the area under the curve where blood pressure exceeds threshold limits.

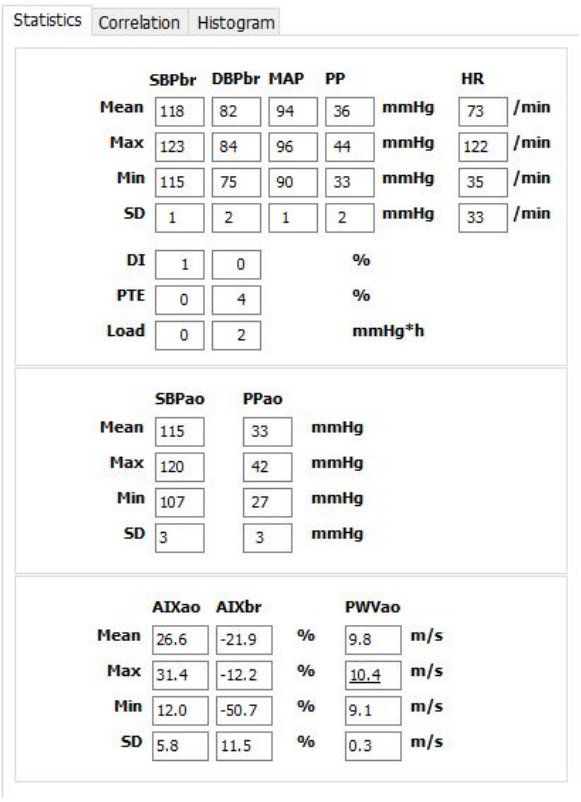


Figure 29 - Statistics

II. Correlation Tab

To display the correlation between systolic and diastolic blood pressure in the recorded data.

- AASI (Ambulatory Arterial Stiffness Index):
  - A measure of arterial stiffness, calculated as 1 minus the regression slope of diastolic upon systolic pressure.

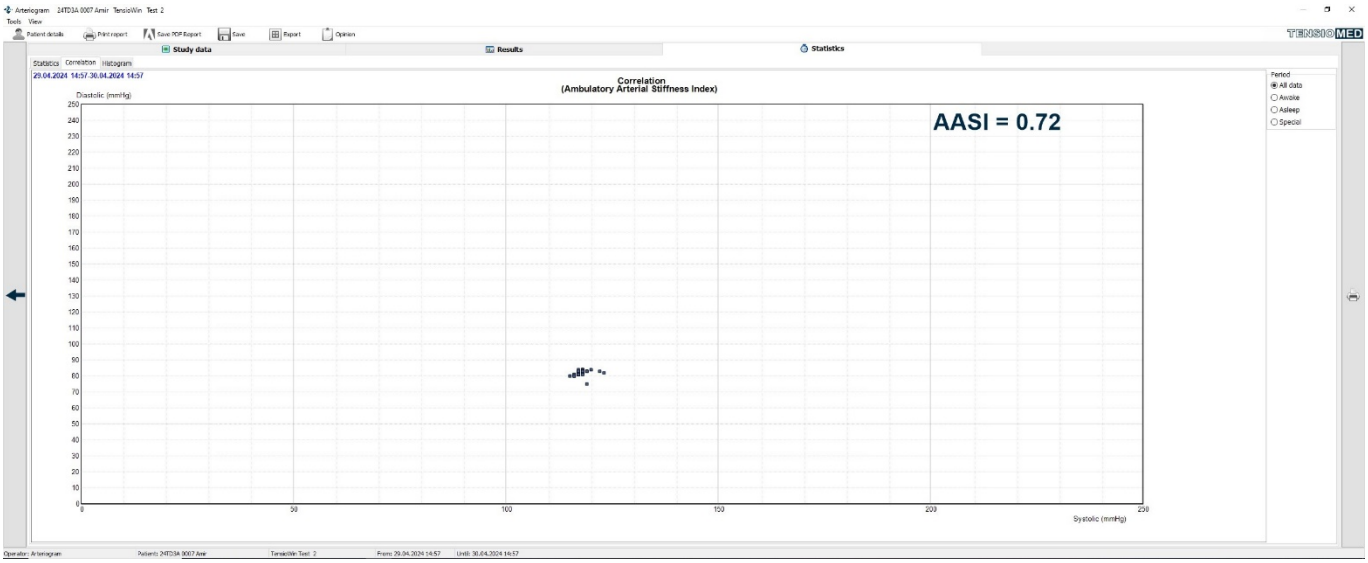


Figure 30 - Correlation tab

III. Histogram Tab

Displays percentages of values within specific ranges for the following parameters:

- ✓ Systolic Blood Pressure

- ✓ Diastolic Blood Pressure
- ✓ Mean Arterial Pressure (MAP)
- ✓ Heart Rate (HR)

Display Options:

- ✓ All data
- ✓ Active period
- ✓ Passive period
- ✓ Special period (if defined)

To print specific data, select the desired period in the “Period” list.

To view plots for the full test or a specific time segment, go to the Results Window and set the Time Segment in the Analysis section.

Figure 31 - Histogram tab

7.4. Opinion

You can easily add an opinion about the current measurement by clicking the “Opinion” icon in the toolbar.

- ✓ Opinion Window Layout:
  - o The upper section displays previously added comments.
  - o The lower section is an editable field where you can enter a new opinion.
- ✓ Portability:
  - o The opinion window can be moved around while switching between pages of the measurement.
  - o This allows you to view curves, parameters, or statistics while adding or editing comments.

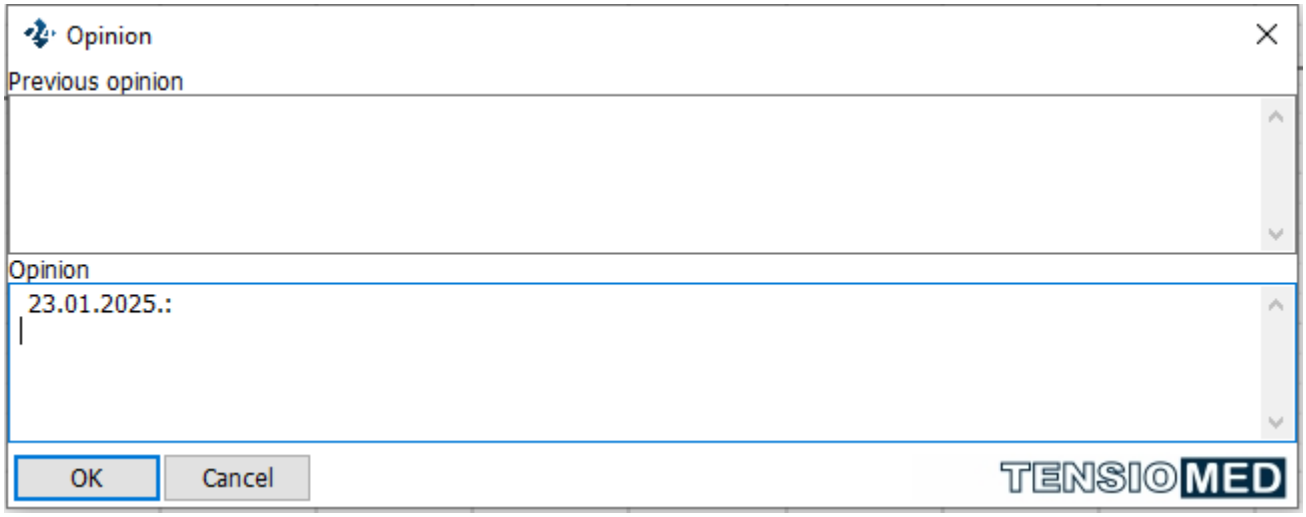


Figure 32 - Opinion window

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 4 report types in TensioWin:

- Report
- Standard report
- Arterial function
- Data

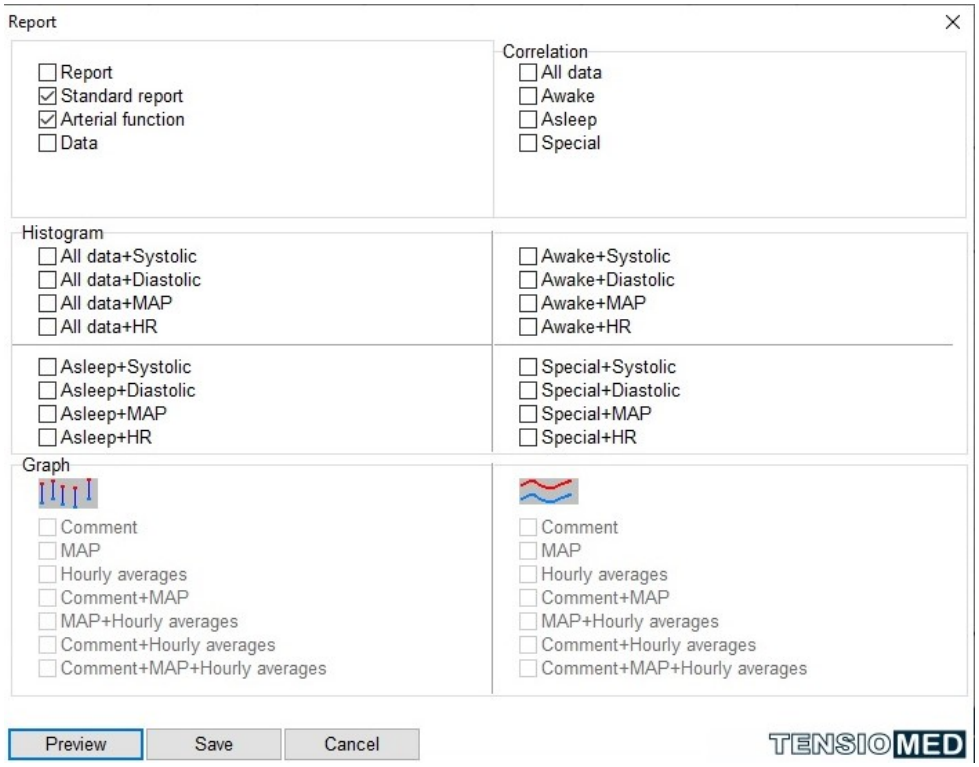


Figure 33 - The settings of the desired report

These types can be printed individually or combined. The selection is performed by checkboxes in the Report window. There are also report elements which can be added/removed to/from the report in this window.

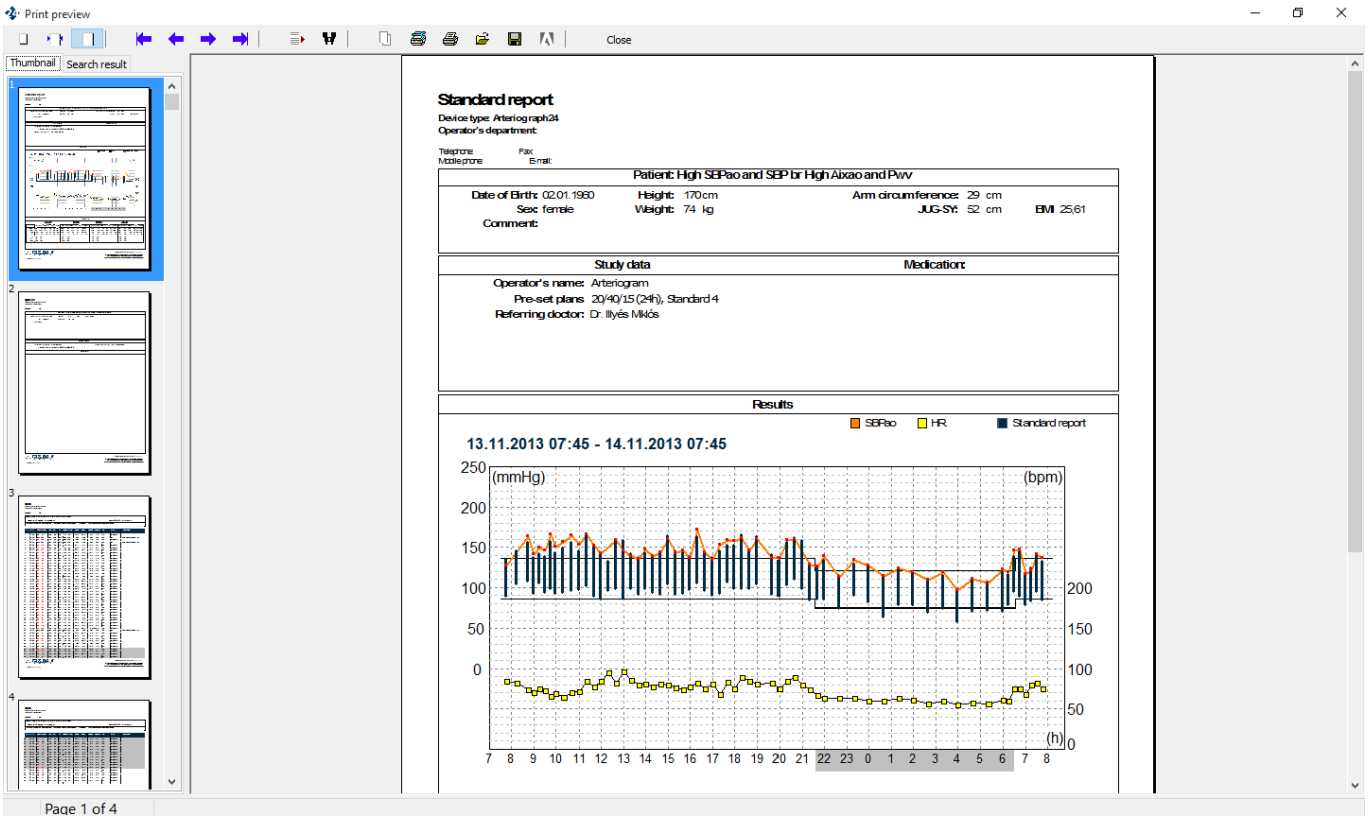


Figure 34 - Print preview

8.1. Print preview elements:

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

Zoom tool

The Print Preview page provides flexible zooming options for better visualization. You can adjust the zoom level based on your preference or screen size:

- Zoom to Fit: This option adjusts the content to fit the height of the screen, allowing you to view the entire page without scrolling vertically.
- Zoom to Width: This setting scales the content to match the screen's width, ensuring the page spans the entire horizontal display area. Scrolling vertically may still be required.
- 100% (Original Size): Displays the content at its original size, representing the actual print dimensions. This is ideal for a detailed, true-to-size review.
- Custom Zoom Percentage (50% to 200%): You can manually select a zoom level between 50% (half-size) and 200% (double-size). This allows precise control over how much of the content you see, which is helpful for both detailed examination and overview.

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

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

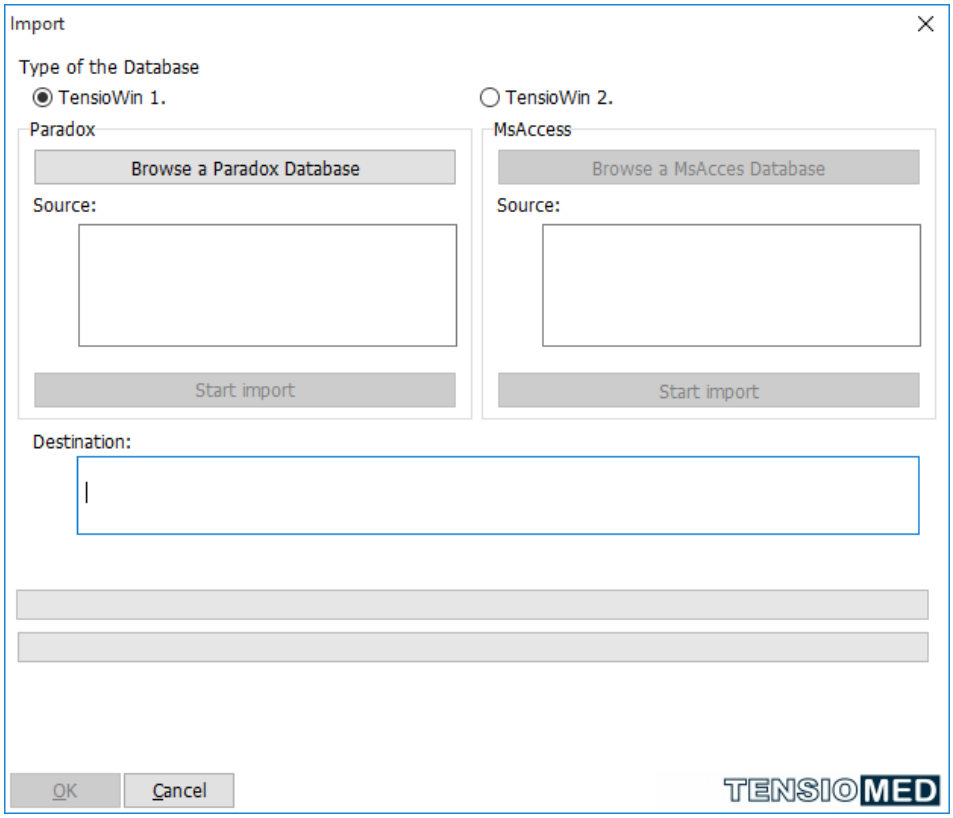
The patient's previously saved reports can be selected and displayed by clicking on Load Report in the Print preview dialog box.

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.



31. Import a database

The process of importing a database is as follows:

1. Access the File Menu:
   - Navigate to the File menu to begin the database import process.
2. Select the Software Version:
   - Choose the version of the software you are importing from:
     - ✓ TensioWin 1
     - ✓ TensioWin 2
3. Activate the Desired Import Option:

- Select the appropriate button for the version you're importing from (e.g., "TensioWin 1").
- This activates the relevant section of the window.

4. Locate the Database File:
   - For TensioWin 1, click on the “Browse a Paradox Database” button.
   - Provide the file path to the database. The default directory is:
   - C:\Program Files\TensioMed Ltd\TensioWin\Data.
5. Start the Import:
   - Once the database location is specified, click the “Start Import” button to initiate the process.
6. Handle the Warning Message:
   - After the import finishes, a warning message will appear.
   - Note the message and proceed.
7. Restart the Program:
   - To finalize the process, restart the TensioWin software.

This ensures the imported data integrates correctly with the new system.

10. What the Characters on the Device Screen Mean

The device first performs the controlling measurement after inserting the batteries as follows:

The voltage control of the batteries. The measured value appears on the display. The supply voltage is sufficient if the measured value is between 6.4 V and 5.4 V.

5.6V

If the voltage drops below 4.4V, the batteries must be replaced. A warning symbol of low battery appears on the LCD.

LOW Batt

If the battery voltage is adequate, the device will be ready for measuring and the current time obtained from the computer will be displayed.

D 09-39

10.1. The Push Button: Different Functions of the Device

- ✓ **One short push of the button starts a manual measurement.**

During the ambulatory measurement mode, there might be a need for manual measurements, for example when the patient feels unwell. One short push of the button starts the measurement. The exact time disappears from the display and then:

- the test pattern of the display appears (see adjacent figure)

- the voltage level of the batteries is checked (see adjacent figure)

5.6V

- calibration takes place, setting the zero pressure level (see adjacent figure)

CAL 0

After that, the measurement starts by the inflation of the cuff, signalled on the display (see adjacent figure).


87

The device checks the placement of the cuff during inflation. If the cuff on the arm is too loose or not the proper size of cuff has been chosen (e.g. it is bigger), the following sign will be on the display accompanied by a sound signal (beeping). Check the cuff and its tightness and repeat the blood pressure measurement.

CUFF

The deflation of the cuff is shown by the adjacent figure.


69

After this process the device shows the brachial systolic and diastolic blood pressure values.

128/96

Then the pulse rate is shown on the display, and the device stores all the measured data, including the date and exact time.

PUL 68

At any time during a reading the patient can terminate the measurement by pressing the push button once. A termination symbol will appear on the display for 10 sec (see adjacent figure). Then the time will appear, and the instrument is ready for measurement in manual and programmed mode.

OFF

- ✓ **Two short pushes on the button** (Pill)
  - Medication Intake Logging:
    - ✓ The time and date of medication intake can be recorded by pressing the button twice quickly after the medicine is taken.

Pill

- ✓ Multiple doses throughout the day can also be recorded using the same method.

- Data Transfer to the Doctor:
  - ✓ All logged data can be transferred to the physician's computer during a consultation.
- Medication Monitoring:
  - ✓ The logged data can be reviewed by the doctor to check how well the medication schedule is being followed, and adjustments can be made if necessary.

This feature ensures that the medication intake is tracked and monitored efficiently.

If the memory of the device is full, this sign will appear on the display.

FULL

✓ **Three short pushes on the button**

D 09-39

N 20-39

allows the patient to indicate the time of going to bed and waking up in the tabulated list of measurements. The device indicates the waking up by a "**D"** letter**.** When the patient goes to bed, "**N**" is depicted.

✓ **Four short pushes on the button**

OFF

The device can be switched off. You will see "OFF" on the display. In this state the series written above cannot be applied and the measuring plan you set in the device will be interrupted. If you intend to use the device again, press the button again four times. Then "OFF" will disappear from the display, all functions of the device can be used again, and the set measuring plan will be continued.

Note: To switch off the device properly and cut its power consumption, remove at least one battery from the device.

11. Troubleshooting

During use, certain error codes may appear on the device display to indicate issues encountered during measurement. These codes are designed to help identify the cause of a problem and guide corrective actions. However, it is important to note the following:

- Single Error Occurrences: If an error appears only once, no immediate conclusions should be drawn. Patient movement or external factors can often trigger temporary errors.
- Measurement Interruptions: When the device is unable to measure blood pressure (e.g., due to patient movement or interference), the measurement will automatically be interrupted to ensure data accuracy.

Understanding and responding to error codes appropriately helps maintain the reliability of the measurements. The meanings of the error codes shown by the device are as follows:

1	The device could not measure the patient's blood pressure within the allowed measuring time frame.
3	The measurement was interrupted due to low battery voltage level.
31	The cuff is not connected to the device.
32	The cuff tube is broken, or something got into the tube (e.g. water).
33	The cuff (or device) is leaking.
34	The cuff is not on the patient's arm.
35	The measurement was interrupted for some reason (e.g. because the patient pressed the button).
37	During the blood pressure measurement, the cuff pressure has reached or exceeded the maximum allowable pressure of 300mmHg 's value.
91-97	The blood pressure measurement was not successful due to the failure of the device, or the batteries are depleted.
100	The measured result cannot be considered as a real blood pressure value, or the patient has arrhythmia.
101	The measurement circumstances e.g. the moving of the patient, disturbs the measurement.
102	The device cannot obtain the heart rate.
110	The measured result cannot be considered as a real blood pressure value because of some movement or arrhythmia
111	The brachial systolic blood pressure is higher than the maximum inflation level.
115	The heart rate cannot be considered as a realistic value.
116	Not enough evaluable systolic and/or diastolic values.

11.1. Sound signals

- During device operation a beeping sound can be heard when pressing its button.

11.2. Instructions for Using the Device

- Programming Responsibility:
  - ✓ Programming the Arteriograph24™ should be carried out by someone familiar with its software and after reading the instructions for use. However, only a physician can determine the medical indication for the measurement and evaluate the results obtained.
- Cuff Selection and Placement
  - ✓ Choosing the Right Cuff: Ensure the cuff size matches the guidelines outlined in subsection 2.2.
- Placement of the Cuff:
  - ✓ Fit the cuff on the right arm with the tube exiting upward over the brachial artery.
  - ✓ Ensure the tubing allows unrestricted airflow.
  - ✓ For added comfort, the cuff can be placed over a thin, long-sleeve shirt.
- Connecting the Cuff:
  - ✓ Insert the cuff's air connector into the device's air connector (refer to Figure 1).

Important: Connect properly by twisting the plug until you hear a clicking sound.

- Patient Instructions:
  - ✓ The patient should avoid muscle movements, especially in the arm, and remain still during pressurization and deflation of the cuff.
  - ✓ Speaking or unnecessary movements should be avoided as they may cause measurement errors or prolong the process.
- Diary Maintenance:
  - ✓ Encourage the patient to keep a diary noting activities, symptoms, sleep times (bedtime and waking), and medication intake.
- Measurement Duration:
  - ✓ Standard Duration: The Arteriograph24™ is designed for 24-hour measurements.
- Extended Duration:
  - ✓ Although it supports longer periods (e.g., 48 hours), the physician must carefully evaluate whether the extended measurement period provides significant clinical value to justify any inconvenience to the patient.

By following these steps and precautions, the Arteriograph24™ can deliver accurate and reliable data while ensuring patient comfort and compliance.

12. Specifications

Power Source:
4 alkaline batteries, size AA
The mode to prevent electric shock:
The device is internally powered, has a low voltage source
The category to prevent electric shock:
CF type patient - part
Display:
Liquid Crystal Display
Data Storage:
EEPROM, Flash memory
Data Transmission:
Bluetooth at least v2.0, Class II, 115200 bps
PC interface:
Bluetooth communication
Computer requirements:
Windows 10 or 11
Operating ambient temperature and humidity:
10 – 40 °C (50 – 104 °F); 15 – 85 % non-condensing
Operating pressure range:
700 hPa – 1060 hPa
Transport, storage temperature and humidity:
-20 – 50 °C (-4 – 122 °F); 15 – 85 % non-condensing
Size:
116,0 × 94,0 × 47,0 mm
Weight:
250g (including batteries)
Blood Pressure measurement method:
Oscillometric
Data Storage:
Max 1000 measurements
Blood Pressure (BP) and heart rate (HR) measurement range:
BP 30 - 280 mmHg; HR 40 – 200 / min
Static accuracy:
±3 mmHg, or ± 2 % of the measured value
Measuring accuracy:
Systolic: 94 out of 99 comparisons were within 5 mmHg (95%), in case of 33 out of 33 patients, 2 comparisons out of 3 were within 5 mmHg, 0 out of 33 patients, where none of the measurements out of 3 were within 5 mmHg Diastolic: 93 out of 99 comparisons were within 5 mmHg (94%), in case of 32 out of 33 patients, 2 comparisons out of 3 were within 5 mmHg, 0 out of 33 patients, where none of the measurements out of 3 were within 5 mmHg Average difference from the auscultatic (Korotkov) measurements: (systolic / diastolic): 0.5/-0.4 mmHg The range of the difference (systolic/diastolic): 2.8/2.8 mmHg
Pressure sensor:
Piezo-resistive
Inflation:
Automatic motor-driven pump
Safety:
Maximum inflation 300 mmHg; Maximum measurement time: 180 seconds
Deflation:
Automatic, stepwise

12.1. Electromagnetic compatibility

Electromagnetic emissions		
The Arteriograph24 TD3A device is intended for use in the electromagnetic environment specified below. It shall be assured that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11:2009 +A1:2010	Group 1	The Arteriograph24 TD3A device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11:2009 +A1:2010	Class B	The Arteriograph24 TD3A device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2:2005 +A1:2008+A2:2009	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3:2013	Not applicable	

Electromagnetic immunity			
The Arteriograph24 TD3A device is intended for use in the electromagnetic environment specified below. It shall be assured that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Conducted discharge: ±8 kV Air discharge: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5:2005	±0,5 kV, ±1 kV line-to-line ±0,5 kV, ±1 kV, ±2 kV line-to-ground ± 2 kV for input/output parts	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	3 A/m	Test level: 30 A/m Test time: 60 s	If image distortion occurs, it may be necessary to position the Arteriograph24 TD3A device further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic immunity

The Arteriograph24™ TD3A device is intended for use in the electromagnetic environment specified below. It shall be assured that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6:2013	1 V_{eff} 150 kHz – 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Arteriograph24 TD3A device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \frac{6}{E} * \sqrt{P} = 2 * \sqrt{P}$ $d = \frac{6}{E} * \sqrt{P} = 2 * \sqrt{P}$
Radiated RF IEC 61000-4-3:2006 +A1:2007+A2:2010	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m on 80 – 1000 MHz and 1,0 – 2,7 GHz frequency ranges AM 1 kHz 80 %	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines do not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Arteriograph24 TD3A device is used exceeds the applicable RF compliance level above, the Arteriograph24 TD3A device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Arteriograph24 TD3A device.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Arteriograph24 TD3A device

The Arteriograph24 TD3A device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Arteriograph24 TD3A device can help prevent *electromagnetic* interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Arteriograph24 device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to *frequency of transmitter*** m		
	150 kHz – 80 MHz d= 2√P	**80 MHz – 800 MHz** d= 2√P	**800 MHz – 2,7 GHz** d= 2√P
0,01	0,2	0,2	0,2
0,1	0,63	0,63	0,63
1	2	2	2
10	6,32	6,32	6,32
100	20	20	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.