

TENSIO MED®



ARTERIOGraph™

Instruction for use

Arteriograph (version: TL2)
Arteriograph Software

CE 1639

TENSIO MED®



TENSIO**MED**[®]

ARTERIO**Graph**[™]

Arteriograph with Arteriograph Software

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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.

This Manual is produced on the assumption that the operator is an experienced user of the Windows 10 or 11 operating system.

If the operator is not familiar with Windows operations, please refer to online help of Windows or the Windows User Manual.

Arteriograph is an unregistered trademark of TensioMed Ltd.

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

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1. Introduction and determination of the intended use of the device

1.1 Preface and determination of the intended use of the device

Thank you for choosing Arteriograph.

The intended use of Arteriograph is for non-invasive examination of brachial blood pressure, heart rate, and central hemodynamic parameters in a medical office. The intended use of the instrument is also to assess the hemodynamic changes created by various factors affecting the arterial circulation (therapeutic effects, physiological changes). Furthermore, the Arteriograph can be used in all areas where non-invasive examination of central hemodynamic parameters is considered necessary by the physician. It is advisable to use the instrument for patients where knowledge of **central** blood pressure and other central arterial functional parameters is desired, but the physician considers that the risk of measurement with a catheter or any other invasive method outweighs the benefits of knowledge of the parameters.

Arteriograph is intended and validated for a **patient population above 3 years of age**. A significant number of independent studies prove the safe and effective use of the device for patients during pregnancy as well.

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

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

If the patient has a **pacemaker**, this does not affect the applicability of the Arteriograph.

If the patient's physiological functions are monitored with **other instruments** (eg ECG, respiratory rate, temperature, oxygen saturation), this does not affect the applicability of Arteriograph. Do not use the device on patients if **high frequency electrosurgical equipment** is applied on them.

For a patient being in a **hyperbaric oxygen chamber**, the Arteriograph should not be used.

In case of a **skin disease or wound on the upper arm** where the cuff is planned to be placed, the Arteriograph measurement should not be performed.

The device cannot be used in case of atrial fibrillation and in other forms of severe arrhythmia (bigeminy or trigeminy) or severe tremor (e.g. Parkinson disease). There is no risk to the patient's health when using the device even in these cases, but the device will most probably not provide any valid measurement results. The less severe forms of arrhythmia do not influence the accuracy of the device.

Regarding brachial blood pressure, the limit values and therapeutic recommendations formulated in the valid national and international methodological guidelines for hypertension apply.

Unfortunately, the limit values and application recommendations for the volumetric analysis parameters on the diastolic record (SAI, DAI, DRA) in methodological guidelines are currently not yet available, although a few studies have been performed to determine the clinical value of these parameters.

*The device is explicitly designed for professional (clinical) use, **not** for public 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, especially in the field of arterial stiffness, of which terms can hardly be translated to the national (local) languages.*

1.2 The purpose of this manual

This manual helps you in setting up and starting to use the Arteriograph (version: TL2) device as well as installing and setting up (on Windows 10 or 11 OS) the Arteriograph Software.



Please read this User Manual carefully before commissioning.



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

1.3 General information

- The Arteriograph operates based on a patented, innovative solution. First, the cuff placed on the upper arm measures the patient's blood pressure using an oscillometric method. After a few seconds, the cuff re-inflates to the measured diastolic value, then to the "suprasystolic" pressure, holding each pressure for 4-10 seconds (adjustable). Once the suprasystolic phase is complete, the cuff deflates, and the measurement ends. This entire process takes up to 2 minutes.
- During the measurement, the device continuously sends data to the program on the computer, where the oscillometric curves, generated by the pulsations of the vascular wall, are displayed in real-time. After the measurement is finished, the program's algorithm analyses the waveforms and calculates the blood pressure and arterial function parameters.
- When active, the device does not cause any electromagnetic disturbance and its immunity to environmental effects is also sufficient. The measurement data are transmitted to the PC through wireless Bluetooth communication. The electromagnetic compatibility between the device and the PC is guaranteed (see Section 7.1 for details).
- To ensure the optimal performance and precise operation, the device should be calibrated at the manufacturer's service every 18-24 months and examined every 3 years.
- Cleaning or disinfection of the cuff sleeve should happen on demand. Under the cuff a light, thin shirt can be worn.

For disinfecting the cuff sleeve the recommended materials are:

- a., Alcohol based disinfectant
- b., Isopropanol (70%)

Please follow the manufacturer's instructions for the use of these cleaners and leave the solution to dry completely.

Avoid disinfecting the cuff bladder and the connected rubber tube. Before the disinfection, pull the bladder and the tube carefully out from the cuff sleeves, until the material allows. The bladder and tube may be damaged by disinfectants.

Do NOT use disinfectants that leave a residue on the product, or which are unsuitable for use in contact with skin.

Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are not sure, remove possible residues with careful washing. **After** removing the hose with the tube from the cuff, the remaining material can be washed in a washing machine at max. 30 °C using a mild washing powder (do not spin). Do not use fabric softeners or other aids (e.g. disinfectant rinses, textile deodorants). For drying do NOT use tumble dryer. It is important to ensure that the disinfectant is washed off completely before setting the cuff in place. Attention, there must be no residual disinfectant on the blood pressure cuff before setting it onto the upper arm.

The Velcro must always be fastened before washing.

- The manufacturer's products should be handled, stored, packaged, protected, and shipped in compliance with the general quality requirements.
- The device meets the requirements of the next standard:
 - IEC 80601-2-30:2018 Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

1.4 Guarantee and life cycle

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, or it is due for supervision, 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!

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1.5 Warnings and precautions



Caution!

Patient safety

The device includes an integrated safety mechanism that prevents the cuff pressure from exceeding 300 mmHg. If inflation continues beyond this value or if the measurement from the first cuff inflation lasts longer than 3 minutes, immediately unplug the cuff tube from the device and remove the cuff from the patient.

Frequent or prolonged inflation of the cuff can disrupt blood flow. Ensure that measurements do not cause extended impairment of blood circulation in the patient's limb.

Ensure that the cuff tube is not kinked during measurement as it may cause prolonged pressurization of the patient's limb.

Do not use the device on an arm, which is being injected with intravenous injection.

Do not use the cuff on burned, irritated or injured skin.

Do not use the device on patients with coagulation disorders, as the cuff's compression on the arm may cause bruising.

If a patient has previously undergone vascular surgery (such as a shunt between the artery and vein) or has a permanent or temporary cannula inserted into the vein or artery for intravenous drug administration, do not place the blood pressure cuff on that arm. Instead, perform the measurement on the other, unaffected arm.

If an extensive mastectomy operation was performed before on a patient on one of the sides of their body, do not install the cuff on the arm on that side!

Do not use the device on neonates or infants! No measurement shall be performed on persons below 3 years of age!

In case of an active skin disorder affecting the arm, or in case of any inflammation type or any wound existing on the arm, please use the intact arm for the measurement. To detect these cases, the patient should be asked before the examination, or the arm should be inspected. If both arms are affected, it is the physician's responsibility to decide whether the value of the data provided by the proposed diagnostic procedure is proportional to the risk that may be caused by the damage that may occur during the diagnostic procedure.

Device use

The user of the Arteriograph instrument is expected to read, understand, and familiarize themselves with the contents of the user manual. While using the software, it is also important for the user to be able to interpret and understand the messages and prompts displayed.

The minimum requirements for the user (operator) include the ability to properly fit the cuff (tight), measure the distance between the upper edge of the sternum and the upper edge of

the pubic bone, measure the arm circumference with a tape, and operate the computer program.

While no special qualifications or education are required to perform the Arteriograph measurement, training from the manufacturer is recommended for optimal use.

*Note, however: the assessment of the measurement results provided by Arteriograph and the determination of the necessary diagnostic/therapeutic steps, will be the responsibility of a **physician** or a **specially trained assistant** with a higher education degree.*

Only use with cuffs supplied by TensioMed Ltd! Use of cuffs supplied by a third party will lead to erroneous measurement results.

If any significant error is suspected in the obtained blood pressure values, confirm the results using the auscultation method.

Do not use a microwave device (e.g. mobile phone) near the unit during measurement.

Any measurement performed with the device when it is exposed to mechanical vibration (e.g. in vehicles) will have unreliable results.

Prevent the device and its accessories to be exposed to direct sunlight, to get in contact with any liquid or from excessive mechanical impact.

Extreme temperatures, humidity, and altitude can affect instrument performance.

Pressurization of the cuff may temporarily cause loss of function of simultaneously used medical electrical equipment on the same limb.

The device cannot be repaired during use. Disassembly or modification of the device is **not** permitted! Please refer to section 1.4. The manufacturer does not accept any liability for damage or malfunction in the event of non-compliance.

The software and device are not designed for network connections. Always install and save the data on a local drive, not in the cloud, to avoid the possibility of an "Access violation" error.

Restrictions of use

The device cannot be used in case of atrial fibrillation and other forms of severe arrhythmia (more than 2 ectopic beats during the suprasystolic operation) or in case of severe tremor (e.g. Parkinson disease). The less severe forms of arrhythmia do not influence the accuracy of the device.

Do not use in presence of tremor as results may be inaccurate.

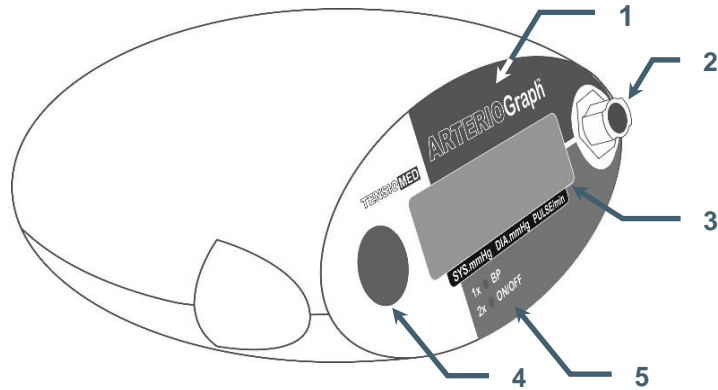
2. The Arteriograph device

This section will give an introduction on the device along with installation information and operation instructions. For detailed specification please see Section 7.

2.1 The device at a glance

Figure 1. shows the front view of the device:

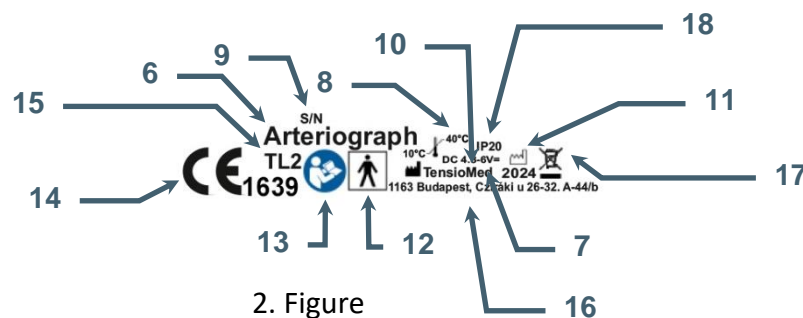
1. The name of the Device
2. Air connector
3. LCD
4. Push button for entering two commands to control the device, as per Section 2.4
5. Symbols standing for the above two commands



1. Figure

Figure 2. shows the device label. The meanings of the symbols are the following:

6. Name of the device
7. Name of the manufacturer
8. Range of ambient operating temperature
9. Manufacturing serial number
10. Applicable nominal range of supply voltage with the batteries
11. Year of manufacturing
12. Safety classification of electric shock protection (Classification: Patient side: BF)
13. Warning on the importance of reading this User Manual thoroughly
14. Certification mark as a guarantee of the device's conformity to EU requirements
15. Type (version) ID of the device
16. Headquarters of the manufacturer
17. Any equipment permanently removed from use shall be disposed of in a selective manner to provide proper reuse and recycling and reduce any harmful effects on human health and the environment
18. Level of protection against any liquid or grainy material leaking into the device (IP N₁N₂)
N₁=2: Protected against solid foreign objects of 12,5mm and greater
N₂=0: Not protected against water



2. Figure

2.2 The accessories of the device

Arteriograph has the following accessories:

- Three cuffs of different sizes (see below)
- Arteriograph software installation in a flash drive including the instruction 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 (see section 5.3 for more information).

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

Arteriograph is a battery-operated device.

- Insert 4 durable alkaline AA batteries into the device while taking care of the right polarity (see Figure 3.)

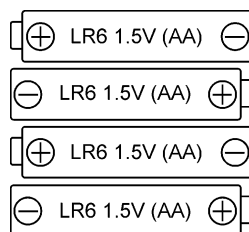
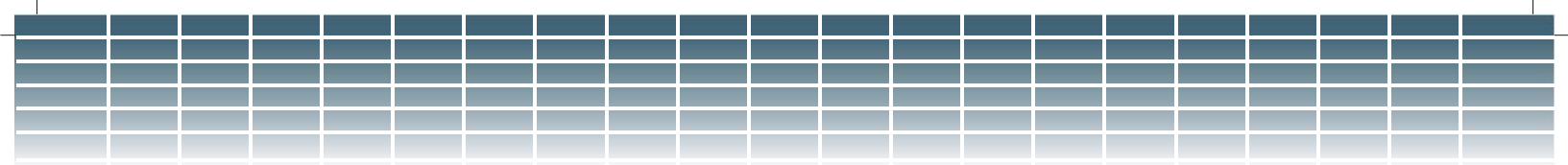


Figure 3.

Note: The clock circuits of the device are supplied by a built-in Lithium CR2032 battery, therefore the operation of the clock is independent from the AA battery supply.



Attention! If you do not intend to use the device for a longer time (more than 1 hour), remove the batteries and store them in a dry and cool place out of little children's reach. Do not expose them to intense heat because it may cause a short circuit. Regarding the alkaline batteries, the policies of use and waste collection as governed by detailed environmental and labour safety requirements are to be considered.



Once the batteries are inserted in the device, the following checks are performed automatically:

- Voltage control of the batteries. The measured value appears on the LCD for a few seconds. The supply voltage is sufficient if the measured value is between 6.0 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**
- The device is ready for operation if the current PC time appears on the LCD. **09-39**

2.4 Operation instructions

There is a single push button available for operating the device (Section 2.1). The user can use the only push button for issuing a total of two commands.

1. **By pressing** the button once, a manual blood pressure measurement will start.
Note! In this case the device performs blood pressure measurement without any arterial function (e.g. PWVao, Aix) evaluation.
2. The device can be turned off by **pressing the button twice**. In **OFF** state the device cannot be operated either manually or by PC. To turn it on, the button must be pressed twice again. **OFF**

2.5. System (Bluetooth communication) setup

Your computer must have active Bluetooth connection capability. The Bluetooth icon appears in the system tray of your PC indicating an active Bluetooth service. For connecting Arteriograph to the PC see Section 5.2. Data transmission can only be performed with the Arteriograph software.

3. The software

3.1. Arteriograph software installation and setup

3.1.1 Preliminary information about the software

The Arteriograph software is designed for Windows. It uses standard Windows mouse functions, such as left single-click, double-click, drag, and others.

The Arteriograph software lets you perform arterial function measurements, print and share the measurement report, and modify the measurement settings.

3.1.2 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.

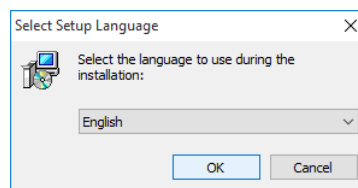
3.1.3 Software Installation

For installing the Arteriograph software on the computer, the user must have administrator privileges.

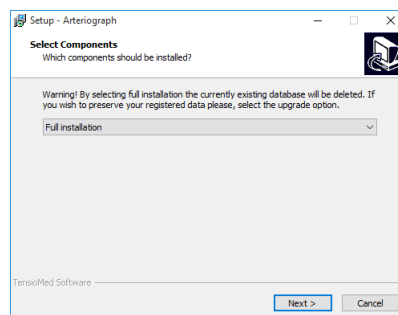
- Step 1 Insert the pen drive into the USB port of your PC. The installation will start automatically. If it doesn't, open the file manager, and double-click the setup.exe file on the disc or flash drive to begin the installation.

If a security warning appears, click "Yes" to continue with the installation.

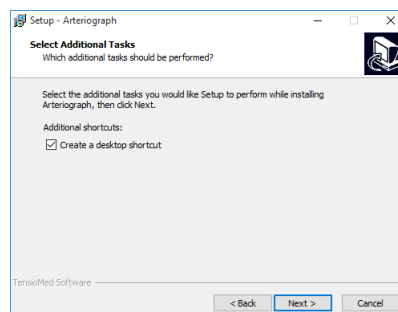
- Step 2 To start the Setup Wizard, choose a preferred language (English is recommended) for installation and click OK.



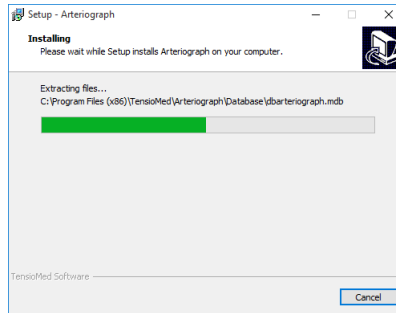
- Step 3 Select the mode of installation from the drop-down list. This can either be Full installation or Upgrade. For the first time, select Full installation. When the preferred method is selected, click Next.
Note: if Full installation is selected on a computer which already contains an Arteriograph database, that database may be lost!



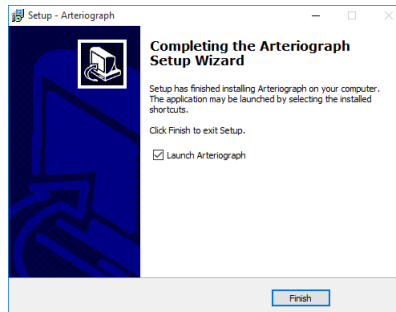
- Step 4 The following screen offers you to create an icon on the desktop. This task can be deselected. Click Next to start the installation process.



Step 5 The status of the automatic installation procedure can be tracked on a progress bar. If you want to interrupt it, click Cancel.



Step 6 When the automatic installation procedure is completed, the following screen appears. Click Finish to exit the Wizard and start the Arteriograph software.



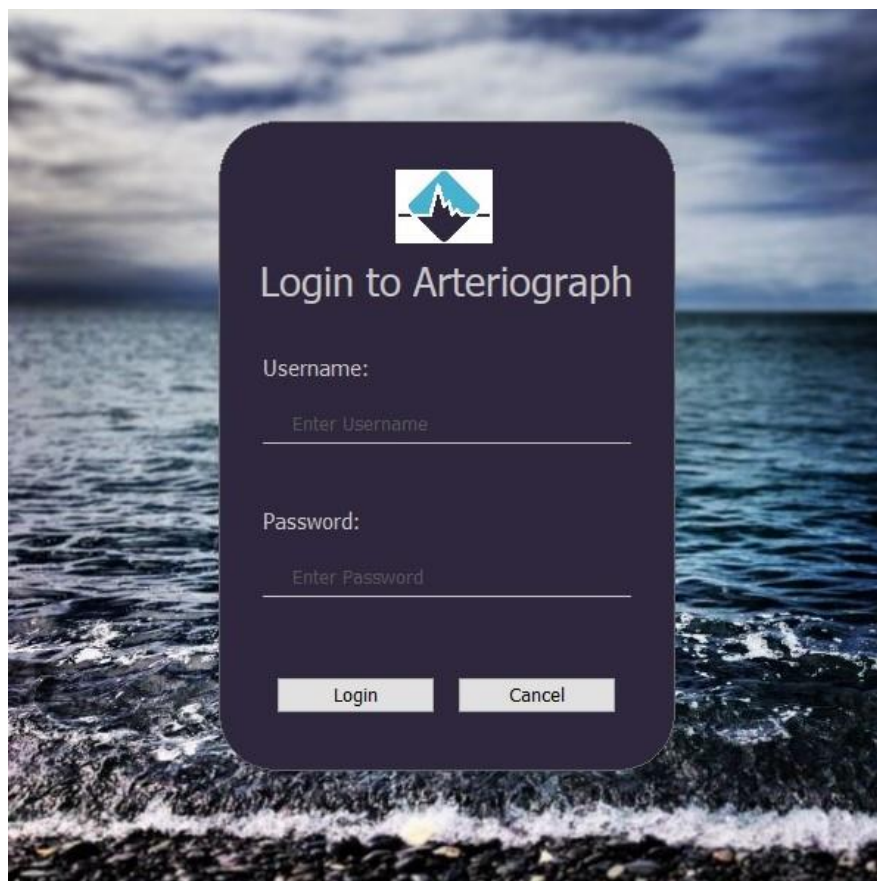
3.2 The software at a glance

To start the Program, double-click the Arteriograph icon on your desktop, or use the Windows Start Menu to navigate to the Arteriograph program.



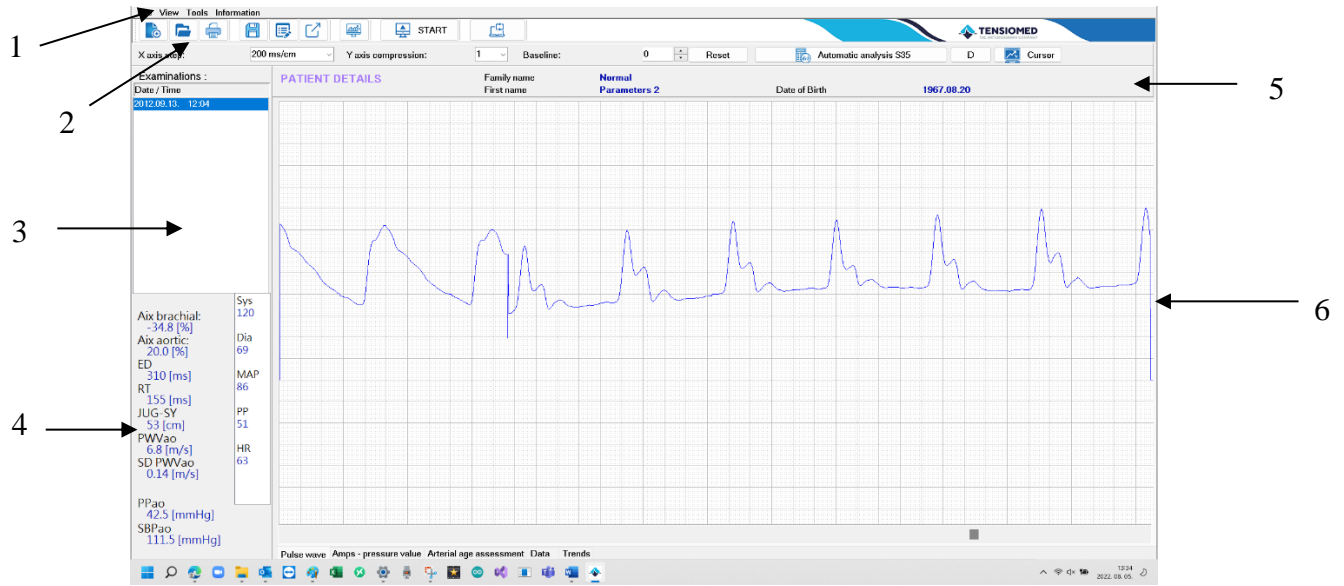
A splash screen appears along with a login dialog window.

The software should be run by the administrator in your institution for the first time (or yourself if you are the only user). Write “admin” to both the “Username” and the “Password” fields. For cybersecurity reasons, however, we strongly suggest modifying these data according to section 3.3. after login.



The program window appears with the following components. (For a better understanding, the picture below shows the program window in the state of a completed measurement.)

1. Menu bar
2. Toolbar
3. List of examinations
4. The primary results tab
5. Patient details header
6. Real-time data display

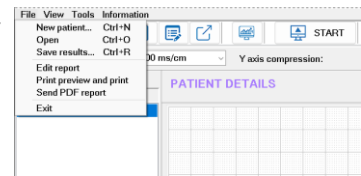


3.2.1. The menu of the program

The menu bar of the software can be found under the title bar and contains the menu items which provide access to all the major functions of the program.

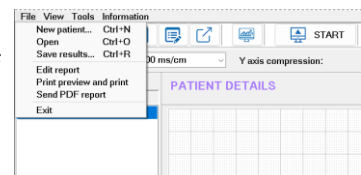
The File menu

The File menu allows entering new patient data; opening, editing or deleting existing records; saving the result of an analysis; furthermore, editing, printing and sending medical reports, as well as exiting the program.



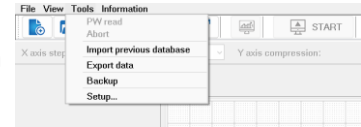
The View menu

The View menu enables the choice to either display the pulse wave records or the maximum amplitudes of the oscillatory signals at each cuff pressure step (deflated stepwise with 10 mmHg) during a blood pressure measurement. Furthermore, you can set both the horizontal and the vertical scale, hide the Toolbar, and get information about the chosen patient.



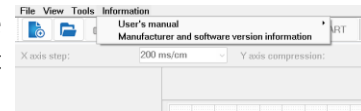
The **Tools** menu

The **Tools** menu provides the functions to start automatic pulse wave data collection processes with the help of the connected Arteriograph device or interrupt an ongoing data collection process. Previous versions of databases can be converted and imported into the new database format. Furthermore, exports and backups of the actual database can be created. All the program and device settings can also be accessed and modified through this menu.



The **Information** menu

General information about the manufacturer and the software are available in the **Information** menu. This menu also includes the present Instruction for use (User's manual).

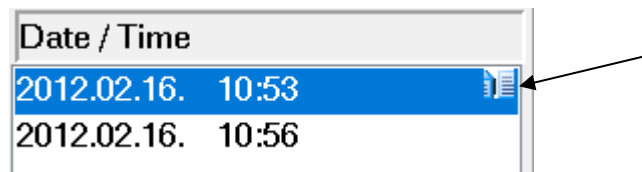


3.2.2 The **Toolbar of the program**

The Toolbar can be found under the menu bar. The displayed icons on this segment provide the means to use the major functions of the product. The Toolbar can be displayed or hidden by the **Toolbar** command of the **View** menu.

3.2.3 The **list of examinations**

All the previous – if there are any – examination records of the selected patient are listed here, sorted by the date and time of recording. If a note is created by the operator for a specific measurement sequence, the software will display the following icon next to the measurement date and time:



3.2.4 The **primary results tab**

The calculated hemodynamic parameters are displayed here when an analysis of measurement data is performed (automatically or manually).

3.2.5 **Patient details header**

The name and date of birth of the patient are displayed on this header.

3.2.6 The real-time data display

After the completion of measurement, the acquired pulse pressure wave graph is depicted on this window in the form of non-calibrated curves (oscillations) as recorded by the device. The recorded and saved pulse pressure waves can be opened and displayed any time.

The user can also select the “Amps- pressure curve” sheet which displays the peak amplitudes of the oscillometric curves obtained in the currently selected measurement, or the “Arterial age assessment” sheet, containing the estimated vascular age of the patient based on the arterial function assessment.



3.3 First step – register a user

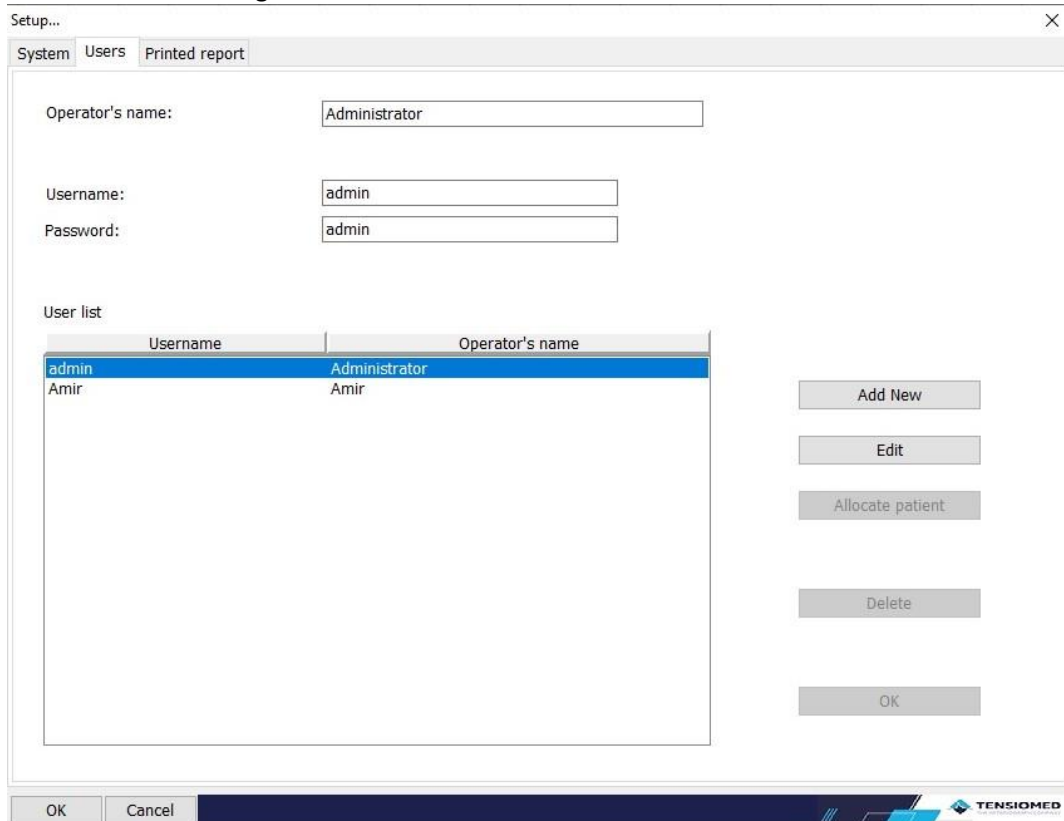
If the program is used by several operators, with each having different groups of patients, users can access their own respective patients’ data after login.

Registering a new user

Only the Admin can register a new user, but each user can update a username or password. Follow these steps:

To Register a New User:

- Open the Tools menu and select Setup.
- In the pop-up window, go to the Users tab.
- Click Add New.
- Enter the operator’s name, username, and password.
- Click OK to save and register the new user in the database.



Note:

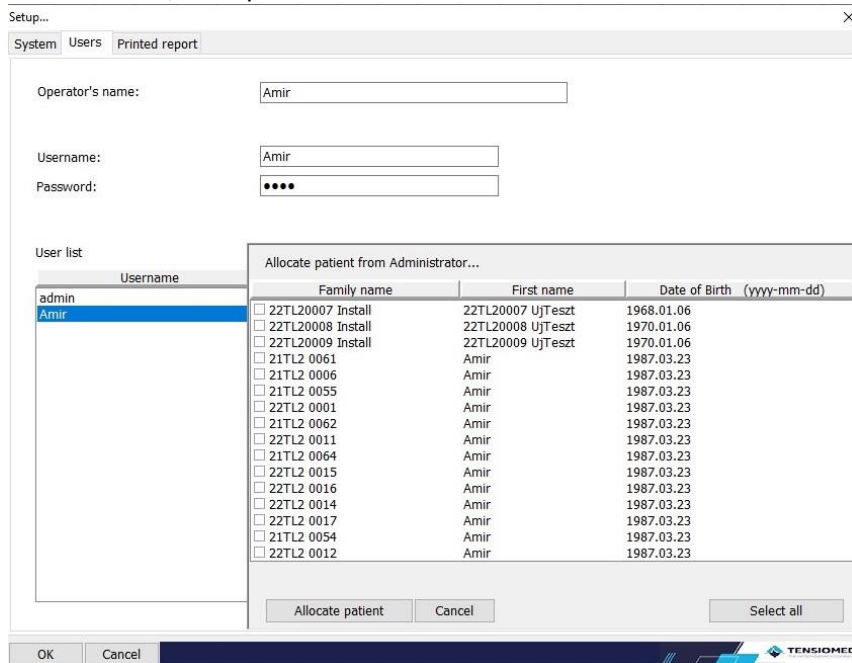
- the settings in the program (COM port number, Auto JUG-SY, etc.) have to be defined for each user separately!

Allocating patients to a user

Each user can manage their own patients and wants to keep patient data private from others. To do this, Admin user can assign patients to a specific user.

- Click "Allocate Patient."
- Choose the patients.
- Click "Allocate Patient" in the new window.

Note: If a user is deleted, their patient data will be moved to the admin account.



How to delete registered users

Only the Admin can delete registered users.

1. Go to the Tools menu and select Setup.
2. In the pop-up window, click on the Users tab.
3. Simply delete the selected user.

4. Performing a simple blood pressure measurement

4.1 Performing the Arteriograph measurement

To operate Arteriograph, first prepare the device (see Section 2.3). There is a single push button (Section 2.1) available for two functions:

- pressing the button once: starting a simple blood pressure measurement/ halting an already started blood pressure measurement. In this case no computer is needed, and the device will work standalone, but it will not provide any arterial function parameter results. The measured systolic and diastolic blood pressure values and the heart rate will appear on the LCD of the device.
- pressing the button twice: switching the device on/off.

The device is ready for operation if the current PC time appears on the LCD.

09:39

Upon starting a simple blood pressure measurement, the current time will disappear from the display and then:

- The LCD test pattern is displayed,

88888888

- The supply voltage is checked

5.6V

- the device calibrates itself by setting the zero pressure

CAL 0

The measurement starts with the inflation of the cuff. This procedure is indicated by an arrowhead pointing upwards.

▲ **87**

During cuff deflation an arrowhead pointing downwards is depicted.

▼ **69**

When the measurement is completed, the device displays the systolic and diastolic blood pressure values,

128/96

and then the heart rate.

PUL 68

The measurement process can be halted any time by pressing the button once. The text “OFF” will appear and remain visible for about 5 seconds on the display. Thereafter the time is displayed again, which indicates that the device is ready for another manual or programmed measurement.

OFF

4.2 Acoustic signals

When the device is active, a soft acoustic signal is emitted when its button is pressed down.

5. Performing pulse wave recording and analysis

Pulse wave recording can only be initialised by the Arteriograph software that is running on a Windows operating system, using a medium with wireless Bluetooth connection to the Arteriograph device (in this case the button of the device is not used to start the measurement)!

The oscillatory signals recorded during the whole measurement process are displayed real-time on the screen.

5.1 Hemodynamic parameters measured by the Arteriograph

The following hemodynamic parameters are computed during the measurement:

Sys – Brachial systolic blood pressure (mmHg)

Dia – Brachial diastolic blood pressure (mmHg)

HR – Heart Rate (beat/min)

MAP – Mean Arterial Pressure (mmHg)

Calculated from the brachial systolic and diastolic blood pressure.

$$\text{MAP} = \text{Dia} + \frac{\text{Sys} - \text{Dia}}{3}$$

PP – Brachial Pulse Pressure (mmHg)

PP is the difference between the systolic and diastolic blood pressure values in mmHg.

ABI – Ankle – Brachial Index (dimensionless index)

The ratio of the ankle systolic blood pressure and brachial systolic blood pressure values.

Aix brachial – brachial augmentation index (%)

Augmentation index = The difference between the amplitudes of the second (reflected) systolic wave (P_2) and the first (direct) systolic wave (P_1) over the pulse pressure (PP) and multiplied with 100

$$\text{Aix} = \frac{P_2 - P_1}{PP} \times 100$$

Aix aortic – central augmentation index (%)

Calculated on the basis of a very strong ($R > 0.9$) linear correlation between the brachial and central augmentation index.

ED – Ejection Duration of the left ventricle (ms)

It is the period of the mechanical systole, i.e. the time interval between the beginning of the heart cycle and the dicrotic notch.

RT – Return time (ms)

The RT is the time of the pulse wave travelling from the aortic root to the bifurcation and back.

PWVao – aortic pulse wave velocity (m/s)

The velocity of the pulse wave propagation in the aorta.

This is calculated from the travelled distance (measured as the suprasternal notch – pubic bone distance) of the pulse wave in the aorta divided by the transit time (RT/2). It relates to the characteristics of the aortic wall. The stiffer the aortic wall, the higher the PWVao is.

SD PWVao (m/s)

A parameter providing information about the quality of the measurement. The PWVao is calculated from each recorded pulse, then the standard deviation is depicted. For more details, see Section 5.4.4.1.

SBPao – aortic systolic blood pressure (mmHg)

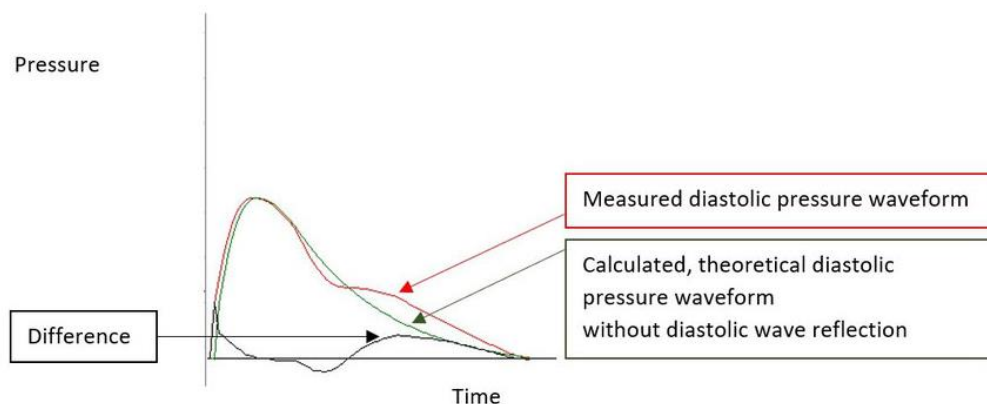
The aortic systolic blood pressure (SBPao) is the pressure in the aorta, and it is considered as an important hemodynamic parameter. It is a result of the ejected stroke volume and the dampening function of large arteries and propagative and reflected pressure waves. It is lower physiologically than the peripheral systolic blood pressure, which is due to different wall structures.

PPao – aortic pulse pressure (mmHg)

The difference between aortic systolic and aortic diastolic blood pressure values.

DRA - Diastolic Reflection Area (dimensionless index)

The DRA provides information on the quality of the left coronary filling conditions during diastole. This parameter is partly based on the duration of the diastole, and on the other hand on the area difference, calculated without wave reflection in the diastole (theoretical, mathematically calculated) and the actual recorded pressure at the diastole with diastolic wave reflection. I.e., the theoretical diastolic pulse pressure waveform without reflection is subtracted from the recorded diastolic pulse pressure waveform. (See Section 5.4.5.)



- ***SAI – Systolic Area Index (%)***
SAI is the systolic part of the area under the entire pulse curve.
- ***DAI – Diastolic Area Index (%)***
DAI is the diastolic part of the area under the entire pulse curve.

Pressurising the cuff to the diastolic blood pressure volumetric signals can be obtained. The area under the curve is taken as 100%, and then it is divided into systolic (SAI) and diastolic (DAI) area and expressed as the percentage of the total (100%).

5.2 System setup

After installation, connect Arteriograph to your medium (e.g., computer) by following the instructions of the enclosed Bluetooth Operation manual.

If during the Bluetooth connection process, a password is required, write 0000.

The device should not be farther than 3 metres from the PC for optimal operation.



Attention! Transmission-blocking objects (e.g. metal objects) can cause signal weakening and consequently malfunction in the communication. The use of the supplied protective pouch does not affect the transmission signal strength, however.

When an active Bluetooth device (e.g. a PC) tries to pair with Arteriograph, the sign shown on the right appears on the Arteriograph's LCD. At this point, no actual data transmission takes place yet.

BLUELINK

Data transfer can only be initiated with use of the Arteriograph software.

5.3 Patient preparation

We have extensive experience with the application of Arteriograph in the 3-90 age group, as our database of tens of thousands of patients has shown that the measurement can be performed in such a wide age range.

There is no direct restriction on the weight of the patients, because if the cuff can be placed on the upper arm in the prescribed manner, and the device is able to collect signals with an adequate quality for evaluation, the examination can be carried out without any problems. Examinations on extremely overweight patients (mostly on the arm) may provide proper results only if the cuff can be placed in a correct way on their upper arm.

There is no specific height limit for the examination with the instrument.

There are no functional obstacles regarding the continuous repetition of Arteriograph measurements, even at time intervals of 2-3 minutes. However, the operator should carefully consider that the patient is unavoidably burdened by a degree of inconvenience in case of performing multiple measurements. Therefore, the value of the information obtained from the series of measurements should be more significant than the above-mentioned side-effect on the patient.

Our studies so far show that a single measurement with the proper preparations detailed in this section is sufficient to judge the patient's cardiovascular prognosis during screening tests. However, taking the average of 3 consecutive measurements results in greater reliability.

Wrap the cuff preferably around the right upper arm. When doing this procedure, please consider the following:

- Use the cuff size suggested by the software (see Section 5.4.2.4.)
- Make sure that the cuff is tightened properly, without causing harm to the patient. The cuff should fit the patient's arm evenly. The tightness is sufficient if your finger cannot be inserted easily under the cuff. The patient should wear clothing that can be easily adjusted or removed to enable application of the pressure cuff to the arm.
- Make sure that the patient's skin is not pinched by the cuff.

Based on expert recommendations, the supine position is suggested for routine arterial function measurements. In case the examination is performed while the patient is seated, indicate this fact in the “Comment” field of the software when the patient’s data are entered. The patient in this case shall sit comfortably, with both feet flat on the ground, with their arms and back supported, and not crossing their legs. Although there were no significant differences between PWVao and Aix in the sitting and lying position regarding the values of these parameters (Hypertens Res. 2011 Feb; 34 (2): 202-8), we recommend a supine position during the Arteriograph examination, because it is more stable from a hemodynamical perspective.

Note: If the cuff is too loose or big, the software may not provide proper measurement results and may display an error message (“Small amplitudes!”).

The cuff should not contact the patient’s chest during the measurement because the respiratory movements may cause pressure alterations and artefacts.

- Place the cuff in a way that the hose is in anterior position and the “ART” (artery) signal on the cuff should look medially, where the brachial artery is located.
- To avoid the irritation of the skin a long-sleeved shirt made of some thin material can be worn under the cuff.
- Lead the hose of the cuff to the device while ensuring that it isn’t compressed or kinked.
- Connect the air connector of the hose to the one on the device. For this, push them together, then twist the plug slightly until it securely clicks. **Make sure that the cuff is properly attached** by checking the tightness of the connection.
- Measure the suprasternal notch – pubic bone distance (Jug-Sy) with the supplied tape measure.

Note: The distance between jugulum (also called jugular notch/suprasternal notch) and pubic symphysis represents approximately the length of the aorta. To obtain this measurement, we must first locate two anatomical landmarks on the surface, using these steps.

Anatomical landmark/surface anatomy to find suprasternal notch:

- At the top of the sternum (breastbone),
- Between the clavicles (collarbones),
- In the midline of the neck,
- Forms a visible depression or notch.

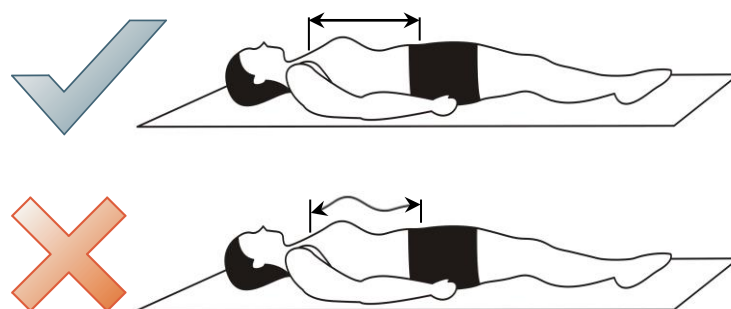
Anatomical landmark/surface anatomy to find Pubic symphysis

- Located in the midline,
- At the lower end of the anterior abdominal wall,
- About 5 cm below a line joining the anterior superior iliac spines,
- Forms a solid bony joint between pubic bones.

Palpation Technique:

- Start 2.5 cm above the pubic hairline,
- Move fingers downward in the midline,
- Feel for a hard, bony prominence,
- Identify the superior border first,
- Can be felt as a firm elevation.

The patient should be in supine position on a flat surface. The jugulum shall be located with a finger and keep “0” on the measuring tape steadily above this point. The measuring tape shall be kept in mid-air, stretched to the location of the pubic symphysis’ upper edge and the corresponding value read directly from above. It is essential to not lay the tape measure on the surface of the body, because if the measured person has a protruding belly, for example, the value measured in this manner may be higher by several centimetres than the correct jug-sy distance.



Note: The Arteriograph software can estimate the Jug-Sy distance based on the height of the patient. If you want to use this function, tick the “Auto JUG-SY” checkbox in Tools/Setup before adding a new patient, and provide their height then.

Communication port: COM	4	<input type="checkbox"/> Auto JUG-SY
Program language	Date format	Login...
English	yyyy-mm-dd	<input checked="" type="checkbox"/> ON / OFF

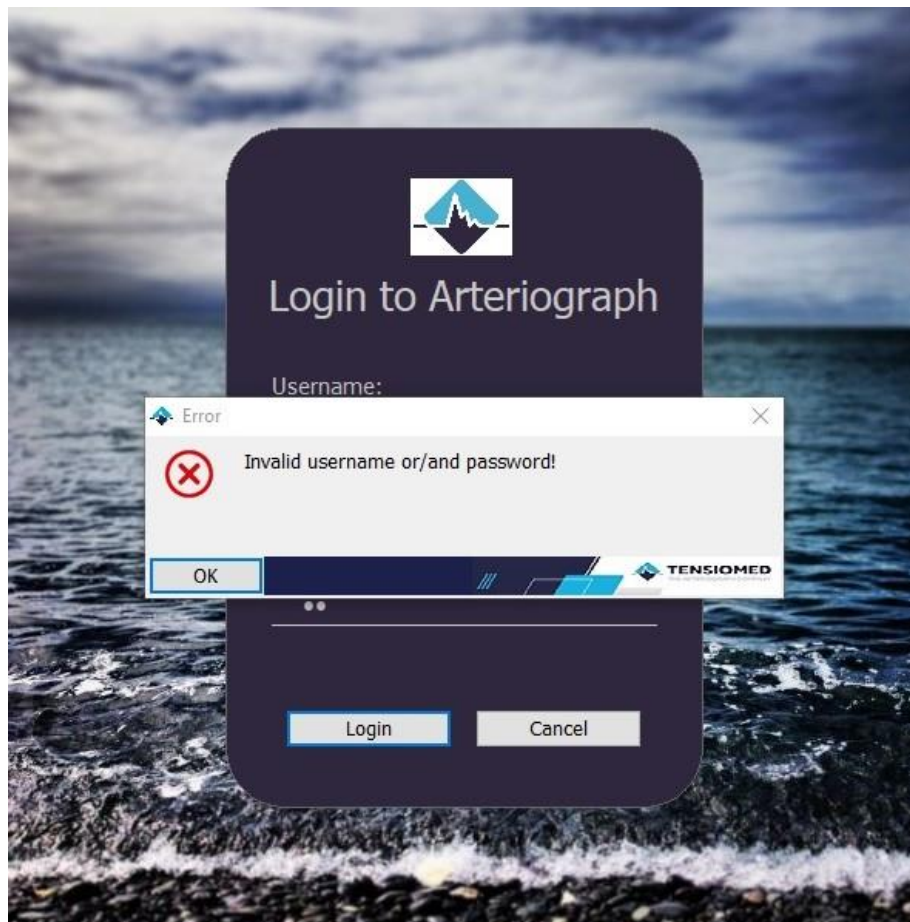
- Ensure optimal measuring conditions:
 - Speaking, muscle movements, especially the movement of arm muscles must be avoided as these activities may significantly increase the measurement time, result in measurement failure, or reduce its precision rate. Sudden muscle movements (tremor) distort the shape of the measured pulse wave and render its evaluation impossible.
 - Within 1 hour before the examination the patient should not consume a greater amount of food, drink coffee/tea or smoke. However, the patient should not be measured in fasting condition, either. A light meal is suggested 1 hours before examination. Drinking enough water is also very important (at least 1 liter in the last two hours before the measurement). Please, empty the bladder. Additionally, within 12 hours before the examination alcohol consumption should be avoided.
 - The patient should take all medication prescribed to them and inform the operator of Arteriograph about the types and required doses of the medications.
 - The patient should not sleep during the measuring phase.
 - At least a ten-minute period of physical and mental rest is required before the examination.
 - Any circumstance (e.g. noise, phone ringing, persons’ movement in the examining room) that may disturb the patient’s calm must be avoided.
 - Should “White Coat Effect” be detected, the measurement must be repeated several times with intervals of a few minutes, or the examination should be repeated another time.

The measurement can be carried out wherever the requirements detailed above are met. The Arteriograph measurement and the evaluation of the obtained parameters can be done in separate locations and at a different time.

5.4 Performing the measurement

To start the Program, double-click the Arteriograph icon on the desktop or use the Windows Start Menu to navigate to the program. If you're starting software for the first time and the default username and password are both set as admin.

If you enter a wrong or non-existent username, the software won't let you access or use it.



5.4.1 Device and measurement setup

Before starting the measurement, changing or checking setup parameters may be necessary.

For setting up the device, select **Setup...** under the **Tools** menu.

Setup...
System Users Printed report

Initial inflation pressure
 Previous MAP + 50mmHg
 Fixed initial inflation pressure [mmHg] 160

Date and time of the device

Download to the device

Set default

Offset of systolic pressure level
-120 mmHg <= 40 <= 120 mmHg

Offset of diastolic pressure level
-120 mmHg <= 0 <= 120 mmHg

Data transfer time at dia and sys pressure level
1 sec <= 8 <= 10 sec

Data Interface: GDT
GDT Directory Browse...

Local Name TSM_ARG2 Local Short Name TARG
Remote Name Remote Short Name

Database: C:\ProgramData\TensioMed\Arteriograph\ Browse...

PDF Directory Browse...

Auto PDF

Calculation of Ankle Brachial Index

Communication port: COM 6 Auto JUG-SY

User defined parameter
Print preview Set

Program language English Date format yyyy-mm-dd Printed report language English

Arterial age assessment
 Show threshold values in the printout

OK Cancel

In the pop-up window the following parameters can be set on the **System** tab:

- **Initial inflation pressure** is the value Arteriograph inflates the cuff to when starting a blood pressure measurement. This can be set as a fixed or a relative value. During the second measurement the device adds 50 mmHg to the mean arterial pressure (MAP) value measured previously and inflates the cuff to this pressure. The relative value is the default setting.
- **Offset of systolic pressure level** determines the value which is added to the measured systolic pressure at the final stage of the measurement, in order to obtain the suprasystolic pressure step where the device will record pulse wave data. 35mmHg is the default setting, which means that data will be collected at a pressure level of the measured systolic value + 35mmHg. For diagnostic examinations this value should not be set lower than 35 mmHg and it is recommended to be set to 45 mmHg to detect the reflected systolic wave more reliably.
- **Offset of diastolic pressure level** determines the value which is added to the measured diastolic pressure to obtain the pressure step where the device will record diastolic pulse wave data (volume curve). Zero (0) is the default setting, which means that data will be collected at the pressure step corresponding to the measured diastolic value. Diagnostic examinations should not deviate from this value.

- **Data transfer time at dia (diastolic) and sys (systolic) pressure level** determines the timespan (in seconds) of pulse wave data collection at the above-specified pressure levels. The default value is 8 seconds. Diagnostic examinations may deviate from this value in the 7-10 seconds range.
- **Communication interface GDT;** The GDT interface enables data transfer between medical devices and the clinic's IT system, based on the standards of the German Quality Assurance Software (QMS). In order to communicate, there is a need for a GDT-supporting clinic software system. To configure the GDT interface, please read carefully and follow the instructions in the GDT Interface Manual on the Arteriograph Installation CD. If the "AUTO PDF" function is selected, the GDT communication automatically saves the test report in pdf format in a directory called PDF.
- **Enter the database path;** The default database path for the software database is "C:\ProgramData\TensioMed\Arteriograph", where the "Database" and "Language" libraries contain the required data files. It is also possible to select another directory, but it is necessary to copy the "Database" and "Language" libraries, with their full contents, from the default location to the new path.
- **Specify the path of the PDF library;** If you select "AUTO PDF", you can select an arbitrary – but writable - directory path where the software can automatically save the test report in a pdf format.
- **Calculation of Ankle Brachial Index;** if selected, the Ankle-Brachial Index is calculated. For this, the ankle systolic blood pressure has to be measured before or after the pulse wave recording (see Section 5.4.3).
- **Communication port;** A default communication port number can be defined here. This way the user can avoid the more time-consuming process of the automatic port search, which may take 20-30 seconds. The proper port number can be checked under Control Panel -> Bluetooth devices -> More Bluetooth settings -> COM ports tab -> Outgoing port number. The program will save the set port number until only one device is used.
- **Auto JUG-SY function;** by selecting this function there is no need to measure the patient's jugulum - symphysis distance. The software will automatically calculate it based on the patient's height, using a large database.

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.

- **User-defined parameter;** One new parameter can be added to the patient's dataset through this function. Enter the name of the parameter into the input field (the parameter will be displayed in the Patient details field on the print-out, see 5.4.6.2) and press **Set**.

Note: The name of the new parameter can be added to a patient's data only once and cannot be modified or deleted later. This parameter will belong to the registered patient data, and it will not be measured by the device, but the value can be modified by the operator.

Non-device-specific settings:

- **Program language:** the language of the Arteriograph software can be selected. The change only takes place upon the next program launch.
- **Print report language:** You can set the language for the measurement report here. However, please note that this setting only applies to the measurement report and does not change the language of the entire Arteriograph software.
- **Date format:** one of the following date formats can be selected: year-month-day, day-month-year, and month-day-year.
- **Arterial age assessment:** By activating this function, the software calculates the patient's vascular age using PWV (Pulse Wave Velocity) data from 60,000 subjects. It compares the patient's PWV to this dataset to estimate their vascular age, which may differ from their actual biological age.
- **Show threshold values in the printout:** To view the threshold values for the parameters measured by Arteriograph, as outlined in the 2023 study "Noninvasive Central Hemodynamic Monitoring in the Primary Care Setting: Improving Prevention and Management of Cardiovascular Diseases," simply activate this feature.

The default settings can be restored by clicking on **Set default**. The settings must be downloaded into the device to take effect. For this, use the **Download to the device** button.

The download of the settings to the device can be tracked on the screen. The text "CONNECT" will be displayed on the LCD of the device while communication is in progress.

CONNECT

Successful data download will be confirmed on the PC.

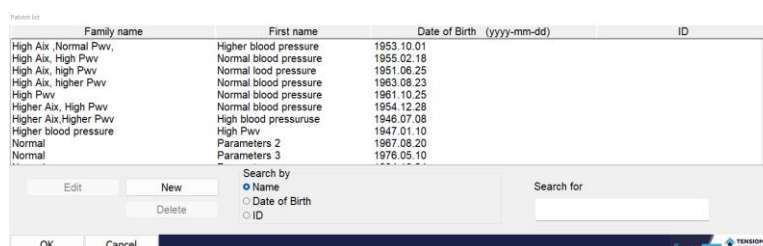
Note: The downloaded settings into the device cannot be cancelled. They can be overwritten by downloading new settings at any time, however.

5.4.2 Select a patient

5.4.2.1 How to select an existing patient



After login to the program, use the **Open** command in the **File** menu or click on the **Open** button (see on the left) on the toolbar for displaying the list of the patients that belong to the current user. Find and select the patient you are interested in (by double-clicking on the row which contains the patient's details or by highlighting the row with a single click and then click on **OK**).



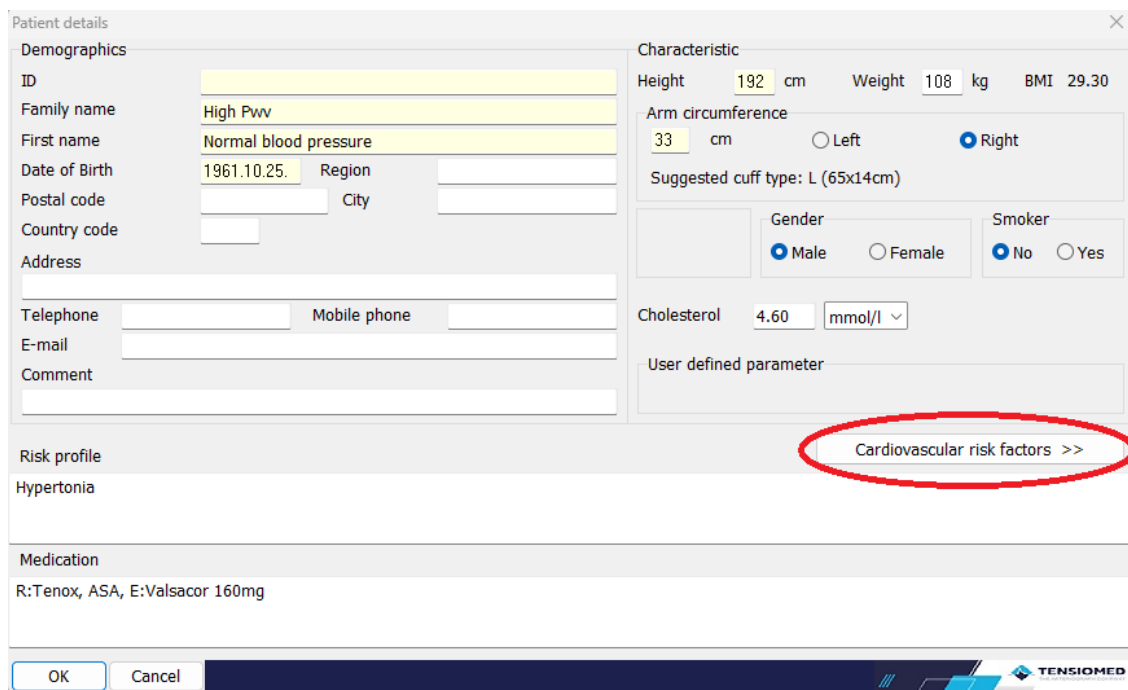
The selected patient’s full name and date of birth are displayed in the Patient Details block under the Toolbar. In addition, the patient’s previous examinations will also appear in a list, if there are any.



5.4.2.2 How to modify a patient’s data

Select the patient (as described above) whose data you wish to modify (by a single click in the Patient list) and press **Edit**. Click on **OK** to save the modified data.

To assess the risk of cardiovascular events of a patient in the next 10 years according to the Framingham Risk Score, click on “Cardiovascular risk factors”.



Provide at least the necessary data (the fields highlighted with a yellow colour) and other applicable data. Select the measurements you want to include in the assessment with their checkbox or click “Select all” then click on the “Risk calc” button.

Cardiovascular risk factors

History

Target organs

Left ventricular hypertrophy

ECG ECHO X-ray

Diabetes

Type 1. Type 2.

Smoking

N/A Never Past Present

Laboratory

Lab date

Cholesterol 110 mg/dl

HDL cholesterol 50 mg/dl

Brachial Blood Pressure

	SBPbr	DBPbr	HR	Date
<input checked="" type="checkbox"/>	136	91	70	2012.02.16.
<input checked="" type="checkbox"/>	140	93	68	2012.02.16.

Select all

Mean values

SBPbr	DBPbr	HR
138	92	69

Risk calc.

OK Cancel

TENSIOMED

The above-mentioned risk percentage will be displayed as a result.

Information

Estimated Risk of Cardiovascular Events in the Next 10 Years Based on the Framingham Risk Score: 7 %

OK

TENSIOMED

5.4.2.3 How to search for a patient

The search function of the software is helpful to find a single patient even in larger databases.

For a quick search click anywhere in the patient list and start typing the required family name. The quick search is not case-sensitive.

An advanced search can be performed by name, date of birth or ID with the help of the "Search by" function. Select "Name", "Date of Birth" or "ID" and type in the name, date, or ID you want to find into the "Search for" field. This function is case-sensitive. When searching by name, the search is made in both the first and last names and even a part of the name can be searched.

5.4.2.4 How to enter a new patient's data



If you want to add the data of a new patient into the database, select the **New patient** command in the File menu or click on the **New patient** button (see on the left) on the Toolbar. For

registering a new patient, only the ID, family name, first name, date of birth, the height, the patient’s jugulum – symphysis (JUG-SY) distance and the upper arm circumference are required to be filled out (those with a yellow background). The jugulum – symphysis distance and the upper arm circumference can be measured with the tape measure provided as an accessory (see Section 5.3). The first data is necessary for calculating the pulse wave velocity while the second one is needed for calculating the proper cuff size. After filling out the arm circumference field, the suggested cuff type and its size will automatically appear next to it.

Note: To achieve a proper measurement quality, always use the cuff suggested by the software.

The cholesterol unit can be selected from a drop-down list (mmol/l or mg/dl).
 The Comment field is advised to be filled out with important information about the patient or the measuring conditions (e.g. the measuring position, pregnancy).
 Fill out the Risk profile field with information on the known cardiovascular risk factors, such as medical history (anamnesis), duration and frequency of smoking, etc.

Note: If the Auto JUG-SY function is activated, the JUG-SY setting will not be displayed on the **New patient** window.

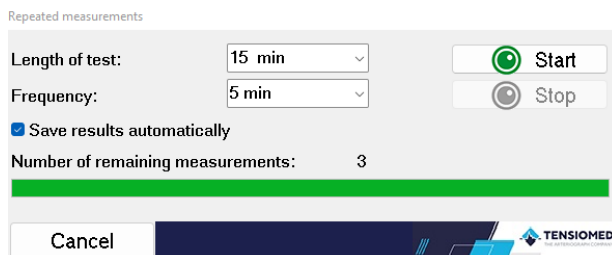
5.4.3 Medical examination with Arteriograph



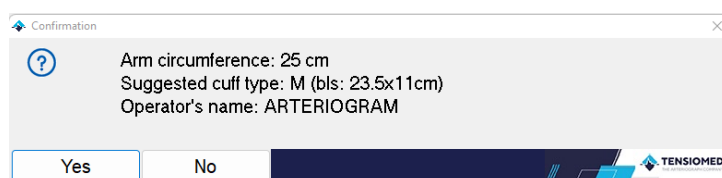
To start a single measurement, select **PW read** under **Tools** or press the **START** button on the toolbar.



To start a scheduled sequence of measurements, click on the **Repeated Measurements...** button on the toolbar. The length of the test and the measurement frequency can be set on the dialog box. To start the measurements, click **Start**. The measurement process can be interrupted by pressing the **Stop** button.



After starting a measurement, a confirmation window will pop up with some important information. If they are correct, press **Yes** to start the measurement process. If these data need to be modified, press **No** and edit the patient characteristics (see Section 5.4.2.2.).



The measurement process starts with the software connecting to the Arteriograph device. First the discovery of the device and active ports, and then the communication process can be tracked on the screen. While this communication is in progress, "CONNECT" (See Section 5.4.1) will appear on the LCD of the device.



After a short time, the measurement will start automatically by performing a blood pressure measurement in the first phase. During measurement, the recorded pulse wave curves can be observed on the screen.

In the second phase, the pulse wave recording for the hemodynamic analysis of diastolic function is performed.

- the device will inflate to the diastolic pressure level and record the pulse waves for a previously determined duration (8 seconds by default).

In the third phase, the device inflates further to the suprasystolic pressure level (by default to the measured systolic value + 35 mmHg), occluding the brachial artery completely, and records the pulse waves for a previously determined duration (8 seconds by default).

(The time and pressure offset values can be modified through the system settings function in the above-described manner. See Section 5.4.1)

During the measurement there is a real-time data transfer, enabling the user to see the recorded oscillatory waves on the screen. At the end of the examination, the device transmits the blood pressure values to the medium (eg., computer) as well. The software displays the following: systolic and diastolic blood pressure values, heart rate, MAP, pulse pressure, and the entire recorded pulse wave curve.



If you want to interrupt the measurement, use the **Abort** command. An **Abort** button appears automatically next to the “PW” button when starting a measurement, and the same command can be found under the **Tools** menu. Please note that this function only halts the data collection procedure of the software and does not affect the operation of the device. To interrupt a measurement on the device, the push button of the Arteriograph shall be pressed once instead.

If the Calculation of Ankle – Brachial Index (ABI) was selected (See Section 5.4.1), a dialog window appears when the suprasystolic pulse wave recording phase is completed. Enter the measured ankle systolic blood pressure here and press **OK**. The calculated value will appear under the blood pressure values in the Primary results tab (see Section 3.2.4). If calculation of ABI is not needed, or the ankle blood pressure could not be measured, press **Cancel**.

Measurement of the ankle blood pressure is advised to be performed before the pulse wave recording. For measuring systolic blood pressure on the ankle, the Doppler technique is suggested. However, if it is not available, the blood pressure measurement can also be performed on the ankle with Arteriograph, using the simple blood pressure measurement function (see Section 4). In the latter case please use the appropriate cuff size (the same rules apply as for arm cuffs, see Section 4.1).

When the measurement is completed, the calculated blood pressure and arterial function data will be presented in the Primary results tab (see Section 3.2.4.), while the recorded pulse wave curves are depicted on the real-time data display (see Section 3.2).



Every examination is saved automatically. A stored examination can be deleted by selecting the row, which contains its date and time in the Examinations list and then pressing the **Delete** button on the keyboard.

5.4.4 Quality control of the measurement

Movements, arrhythmia, respiration, etc. with a disturbing effect on the measuring process may distort the shape of the recorded pulse wave, which may result in false hemodynamic parameter values. Having finished the measurement, its quality should be checked to decide whether the result of the analysis can be accepted.

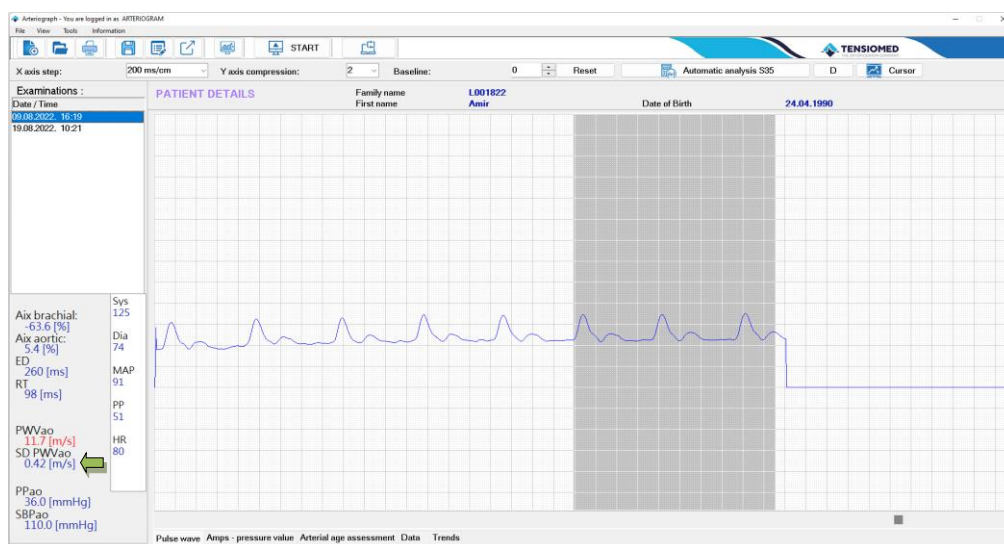
We would like to note that the device and the software are sensitive to the of the input signal shapes' appropriateness. If the software detects artefacts in the signals, it purposely does not provide arterial function parameters.

In case of any measurement with a standard deviation higher than 0.7, you can simply mark those pressure waves that are the most identical in a single measurement and the result will be average of selected similar waves which reduces deviation of obtained data. For this reason, please follow the instructions given below.

1. Select the problematic measurement with the high standard deviation.



Choose three or more measured waves which shows similarity in shape by simply clicking and dragging the mouse from beginning till the end of mentioned waves. The average pulse wave velocity will appear in which the high deviation due to probable operating issues are avoided.



Thus, the accuracy and reliability of the measurements can be significantly increased. As a result, the repeatability (variance) of the PWVao measurement results (the difference between successive

measurements for a patient) showed the lowest variance, i.e. the most favourable repeatability in comparison with other instruments (J Hypertens, 2008, 26: 523-528).

5.4.4.1 Quality control index: the SD PWVao

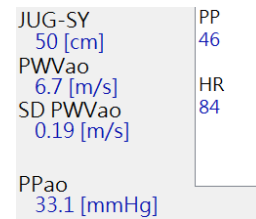
SD PWVao (see Section 5.1) is the standard deviation of the PWVao values calculated using the pulse waves that are analysable by the algorithm of the software. This variable shows how much the PWVao data of each analysed pulse curve differ, therefore reflects on the identity of the recorded pulse wave forms. Large deviation of the measured data shows some disturbance in the measurement.

Normal SD

If the SD PWVao is greater than or equal to 0 and less than or equal to 0.7 m/s, the measurement is of good quality.

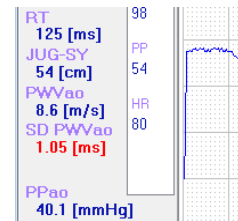
Borderline SD

If the SD PWVao is higher than 0.7 m/s, but less than 1.0 m/s, the quality of the measurement can only be accepted with concerns. Experienced users can use the manual evaluation to search for appropriate waves on the suprasystolic part of the measurement (see 5.4.4.). If the manual evaluation would not provide better (<0.7 m/s) SD, the measurement should be repeated!



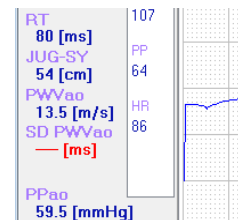
High SD

If the SD PWVao (SD) is greater than 1.0 m/s, the measurement is considered to be of unacceptable quality and the results of the current analysis should be rejected. The SD appears in red colour in the Primary results tab to warn the User about the quality problem.



No SD

If the automatic analysis calculated arterial function data but no SD PWVao, then only one evaluable pulse curve could be found in the suprasystolic measurement sequence. The SD appears in red colour in the Primary results tab to warn the user about the quality problem. The results of the analysis should be rejected, and consequently, the measurement should be repeated.



5.4.4.2 Quality control by visual inspection

While the SD PWVao is effective in detecting erroneous measurements, further visual inspection can help identify the type of error, allowing it to be avoided when repeating the measurement. Disturbances can also be spotted through visual inspection, even in measurements that the SD PWVao classifies as good quality.

If there is no second systolic wave on the pressure curves recorded on the suprasystolic section

Arteriograph can only provide arterial function data when the first (direct) and second (reflected) systolic waves can be detected separately on the pressure curves recorded at the suprasystolic cuff pressure. If these waves are not distinguishable on the suprasystolic pulse curves, the common reasons are the following:

- the cuff is too large or loosely fixed,
- high heart rate (> 90 / min) or low amplitude reflected systolic wave (quite common at young age),
- dehydrated state resulting in reduced circulating blood volume.

Recognition: non-identifiable reflected waves on the suprasystolic pressure curves

In this case the direct and reflected systolic waves cannot be differentiated on the pulse waveform which is always indicated by the software with a warning message.

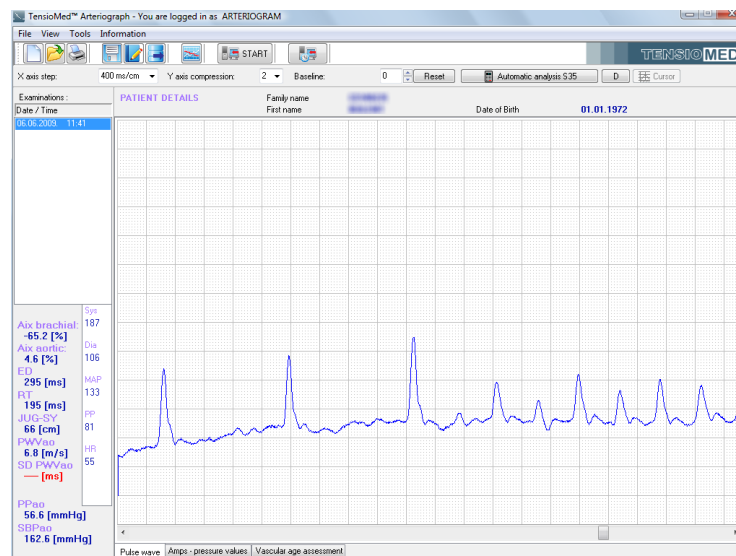
How to avoid: See Section 5.3. Additionally, the solution could be to use a smaller cuff or tighten the cuff according to the instructions.

Arrhythmia

The oscillatory measurement method is highly affected by arrhythmia. In such cases the beat-to-beat variance of the pulse wave forms renders the analysis inaccurate.

How to recognize: the heart beats do not show regularity.

How to avoid: this condition cannot be affected by the examiner. The SD improvement steps (see Section 5.4.4.) can help to find an appropriate sequence in the suprasystolic measurement phase.

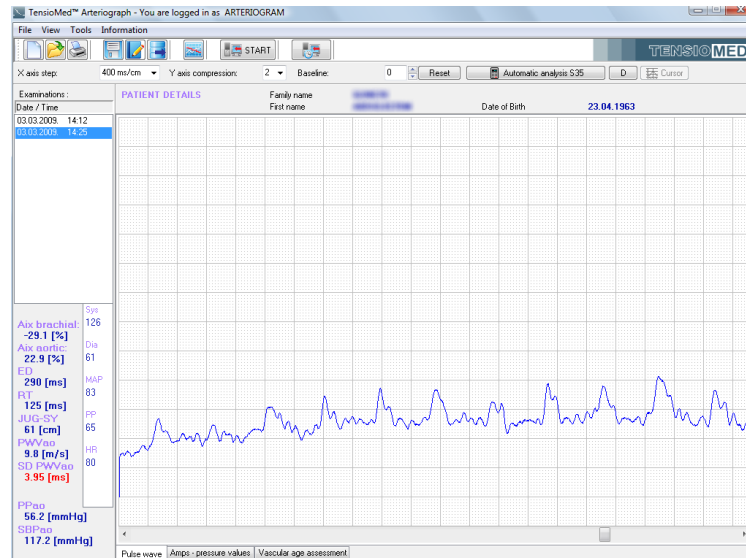


Tremor or mechanical vibration

Tremor introduces an unwanted high frequency noise into the measurement. This often leads to nonvaluable waveforms.

How to recognize: the measurement is noisy; a sawtooth signal is superimposed on the pulse waves.

How to avoid: tremor cannot be affected by the examiner. Make sure, however that the patient is isolated from external mechanical vibration (e.g. do not place the patient's arm onto a vibrating machine, like a PC).

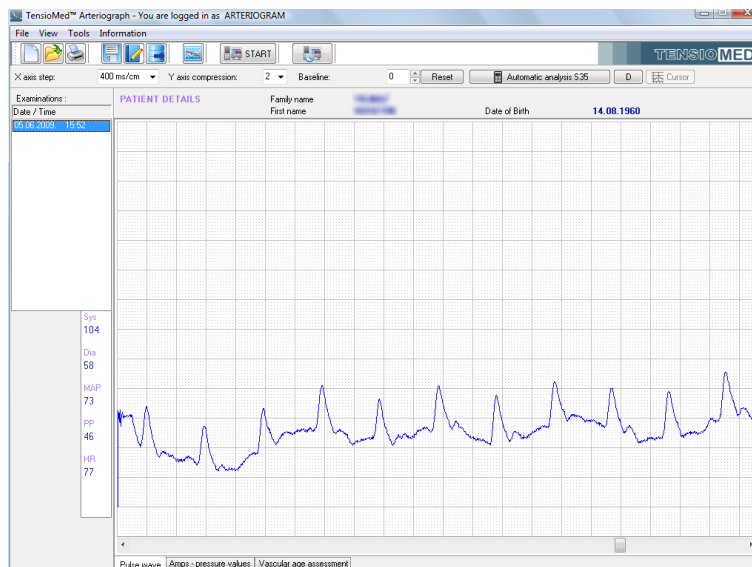


Movement artefacts

Movement artefacts distort the waveforms and lead either to not analysable measurements or to results with inflated variation.

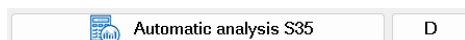
How to recognize: the baseline of the recording undulates, or some pulse waves noticeably differ from the others.

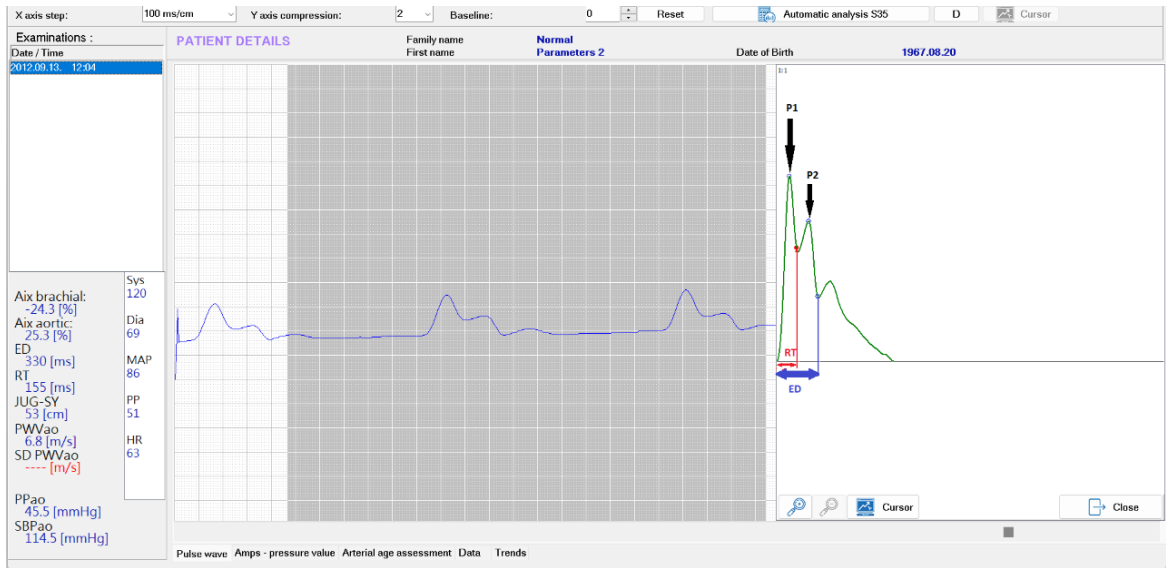
How to avoid: emphatically ask the patient not to move. Manual evaluation (see Section 5.4.5) can help to find a regular sequence in the suprasystolic measurement phase.



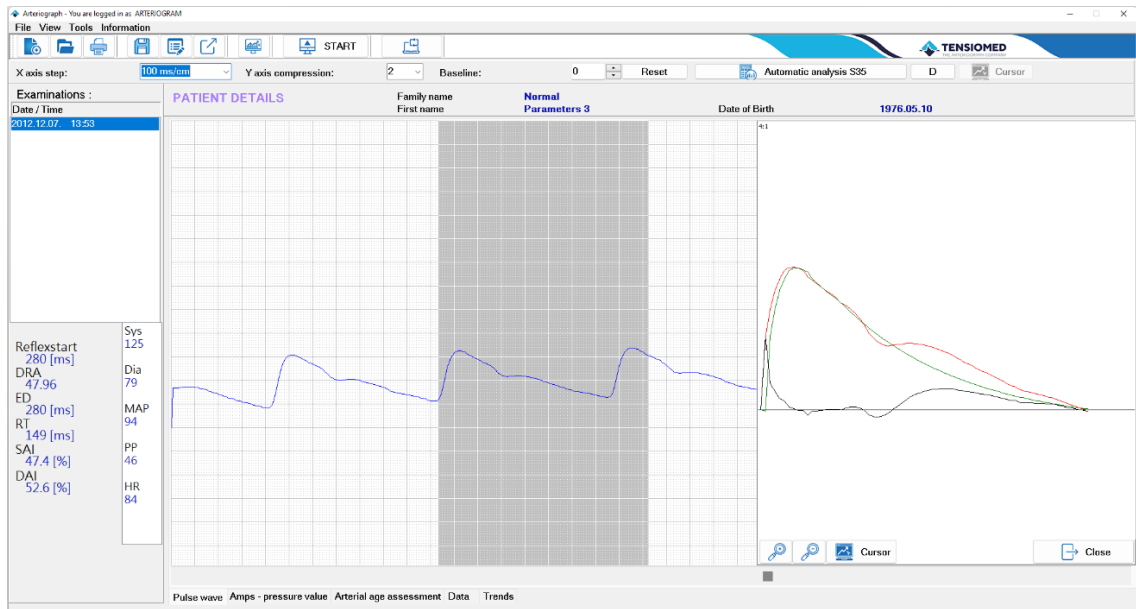
5.4.5 How to analyse the data

Select a patient and one of their examinations you intend to analyse. You have two evaluation options available: automatic and manual.





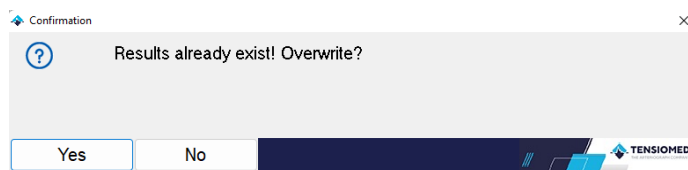
- When selecting only one pulse wave at the pressure step corresponding to the diastolic record, several curves appear in the secondary data display: the recorded pulse wave (represented by a red curve), the pulse wave corresponding to the relevant mathematical calculations (green) and the difference of the previous two (black).



Using the tools in the secondary data display the single pulse wave can further be examined. The curve can be enlarged and reduced in size within pre-set limits; see the current scale in the upper left-hand corner of the window. Furthermore, you can examine the curves from point to point by means of a cursor that can be activated. The secondary data display can be closed separately.



The new findings of the evaluation can be saved into the database by selecting **Save results...** in the File menu or by clicking the **Save results...** button on the toolbar. Any previous result will be overwritten.



Different results from the ones calculated by the automatic evaluation can be saved. An examination is displayed with the formerly saved arterial stiffness results upon opening. If no result is saved, the software displays the results of the automatic evaluation. However, in this latter case no values will be exported with the Export command (see Section 5.4.)

Note: Only the results of the automatic evaluation are saved automatically. For saving the results into the database after a manual evaluation, the **Save results...** command should be used. This allows the examiner to save the results of only those measurements that are of good enough quality to be exported later.

5.4.5.1 Tools for visual inspection

X axis step / Horizontal axis

X axis step:

The scale of the horizontal (time) axis of the pulse wave curve as depicted on the real-time data display can be set from 10 ms/cm to 1,600 ms/cm in pre-defined steps. This function can be accessed directly from the toolbar (**X axis step**) or by selecting a value under **Horizontal axis** in the **View** menu.

Y axis compression / Vertical axis compression

Y axis compression:

Here the vertical (amplitude) axis of the pulse wave curve, as depicted on the real-time data display, can be set. The set value indicates the vertical compression rate of the curve. If the set value is 1, the pulse wave curve (blue) will be displayed in full size. This function can be accessed directly from the toolbar (**Y axis compression**) or by selecting a value under **Vertical axis compression** in the **View** menu.

Baseline shift

Baseline:

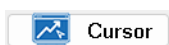
The pulse wave curve on the real-time data display can be moved upwards or downwards in relation to the zero line. The original position can be restored by clicking on the **Reset** button.

View pressure curve



To display the actual cuff pressure values, press the **View pressure curve** button on the toolbar. When it is on, the baseline cuff pressure can be seen during the whole measurement on the real-time data display.

Cursor



Use the **Cursor** function for reading the coordinates of the oscillatory signal (pulse waves) and the value of the baseline cuff pressure (if the **View pressure curve** function is on).



When the button is on, the cursor control tools appear. Using these, the cursor can be moved in single or multiple steps.

Note: The cursor feature is only available at the default **X axis step** of 200 ms/cm.

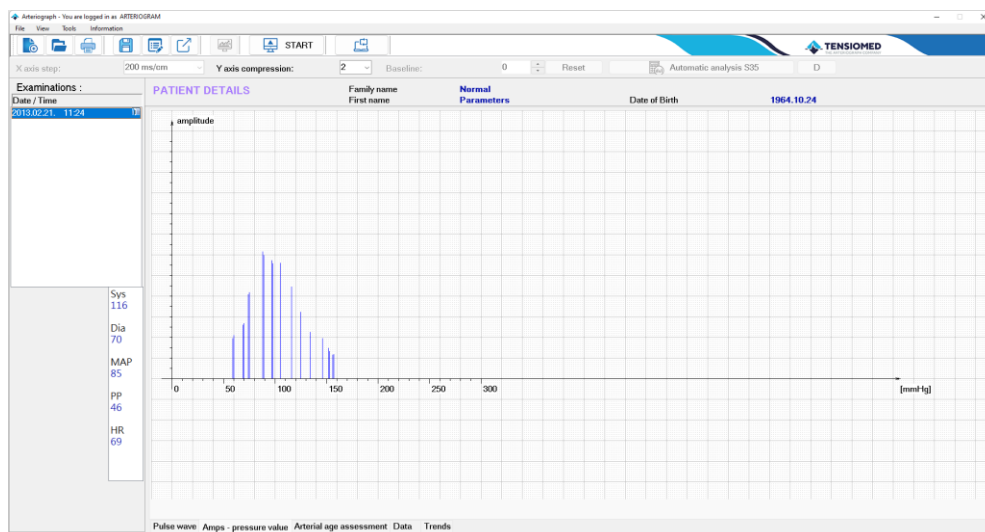
The above-mentioned functions are illustrated in the picture below.

Note: The oscillatory (blue) signals are not calibrated and therefore should not be considered to represent true pressure values.



5.4.5.2 Oscillation amplitudes during blood pressure measurement

By clicking on the **Amps – pressure value** tab of the measurement window, the maximum amplitudes of the oscillations recorded during the blood pressure measuring phase are depicted. The same function can be accessed by selecting the **Amps – pressure values** option under the **View menu**. By using this feature, the quality of the blood pressure measurement can be evaluated visually.



5.4.5.3 Vascular age assessment

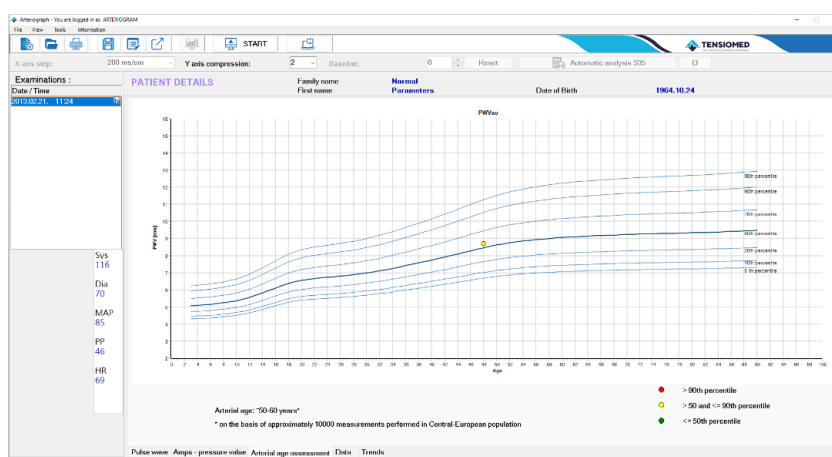
The **Vascular age assessment** tab of the measurement window shows the estimated vascular age of the current patient. This function is found in the **View menu, Vascular age assessment** command. This tab shows the correlation between age and PWVao with smoothed reference percentile curves.

Note: The percentile is a value below which a certain percentage of the known measurements fall, e.g. if the measured value of the current patient is in the 75th percentile, 75% of the reference test subjects had a lower PWVao value than the currently measured patient. The reference data (pulse wave curves) were derived from a healthy central - European sample including approx. 10 000 subjects.

Age-specific percentile curves show certain percentiles in different ages.

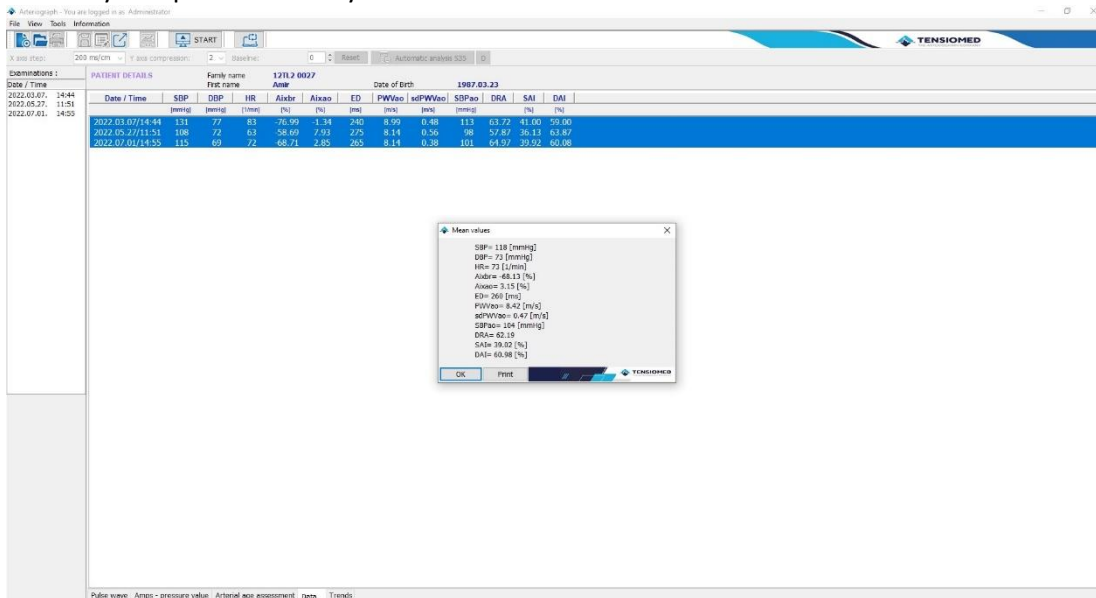
The current measurement is indicated with a coloured dot on the graph, with the colour depending on which range the measured PWVao value falls. The ranges are the following:

- Normal – green colour. The measured value is lower than or equal to the 50th percentile for that specific age group.
- Elevated – yellow colour. The measured value is higher than the 50th percentile but lower than or equal to the 90th percentile for that specific age group.
- High – red colour. The measured value is higher than the 90th percentile for that specific age group.



5.4.5.4 Data analysis

The Data tab displays all measurements for the selected patient. To see the mean values for any parameter, simply select the measurements you want to calculate the mean for, and the software will automatically compute them for you.



5.4.6 The measurement report

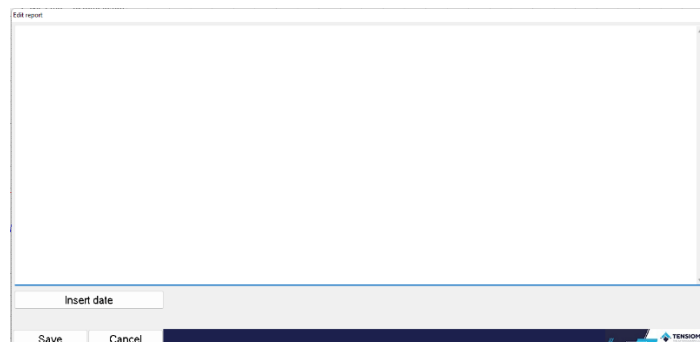
The report is a printed summary of the selected measurement results. It includes patient details, all the calculated hemodynamic parameters, suprasystolic and diastolic pressure curves and vascular age assessment.

The following functions are only enabled if an examination of a patient has been selected.

5.4.6.1 Edit the report



To add or edit information (notes) to the report, press the **Edit report...** button on the toolbar or select the **Edit report** command under the **File** menu. In the report window you can enter your medical advice / treatment suggestions, which can be saved by clicking on **Save**. The current date can be added to the report by using the **Insert date** button. The edited report will appear on the **third** page of the print-out.



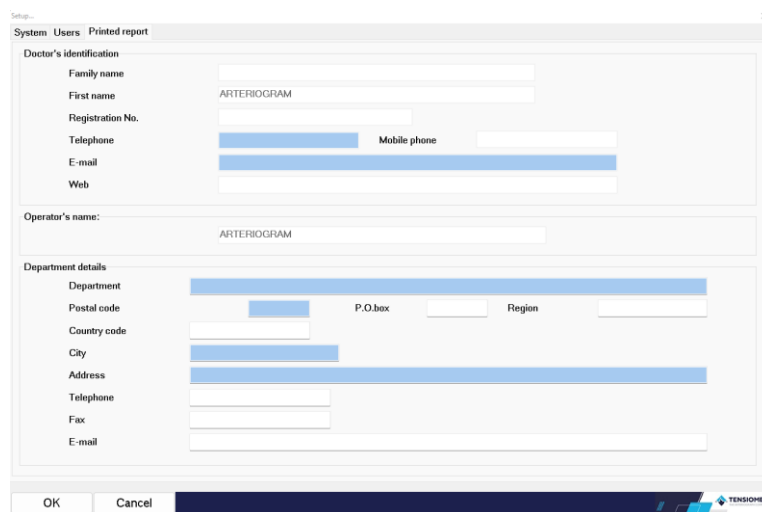
To display institutional data on the printed report, select **Setup** under **Tools**. In the dialog box choose the **Printed report** tab where you can specify the following:

- Doctor's identification data
- Department details

Department details along with the doctor's name and registration number will be depicted in the footer of the printed report. These data are user-specific and therefore will appear on the report of every patient of the user.

The Operator's name is shown in the Measurement data section of the printed report. It is measurement-specific, therefore can be modified for each measurement. By default, the Operator's name is the login name of the User. The Operator's name for the default user (ARTERIOGRAM) cannot be modified.

Note: The report is assigned to a specific examination, and can be modified later. For other measurements of the patient this medical advice will not be saved or displayed.

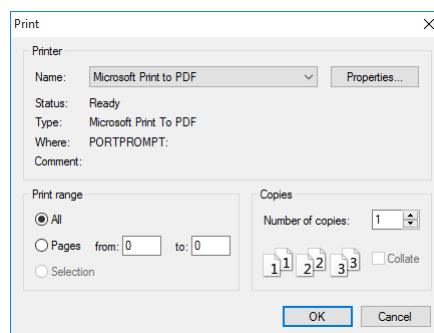


5.4.6.2 Print the report

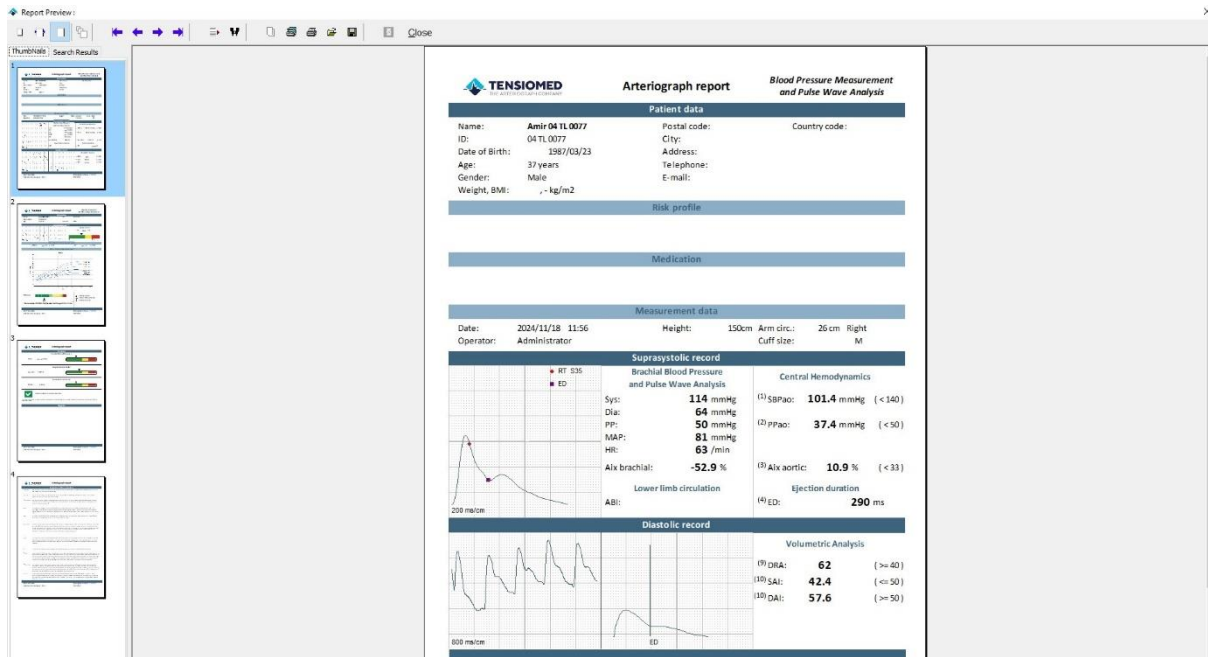


You can print out a report by choosing **Print preview and print** under the **File** menu or clicking the **Print preview and print** button on the toolbar.

A Print options dialog window appears where printer selection and printer settings can be made, and other common print options can be set. Click OK/Cancel to continue.



The print preview screen appears:



Using 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**), to the original size (**100%**), or a percentage value between 50% and 200%.

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



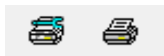
Using these tools, a search can be performed by page number (**Go to page**) or by a keyword (**Search for text**).

Copy tool



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

Print tool



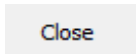
A printer can be selected and set up using the first icon. We recommend Microsoft Print to PDF, as certain pdf writer software may not depict the graphs on the measurement report. The page can be printed with the previously determined settings by clicking on the second icon.

Load tool



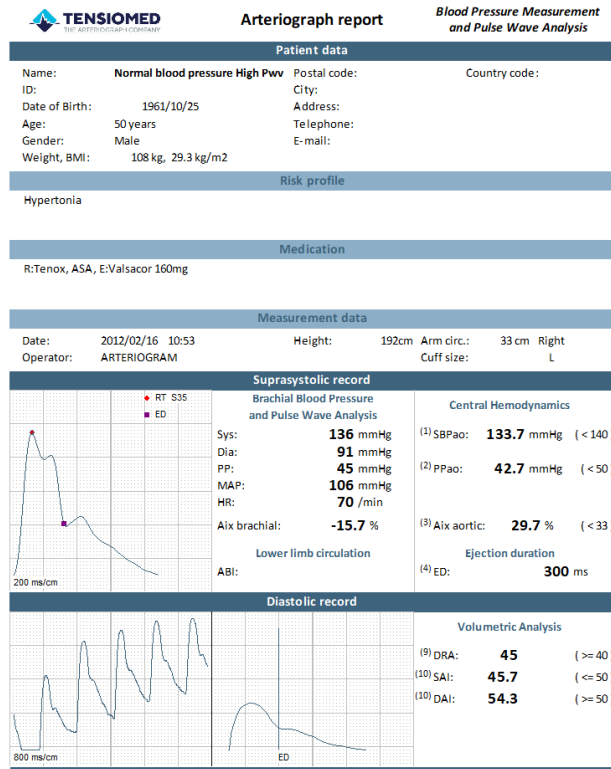
The patient's previously saved reports can be selected and displayed by clicking on **Load Report** in the Print preview dialog box.

Close



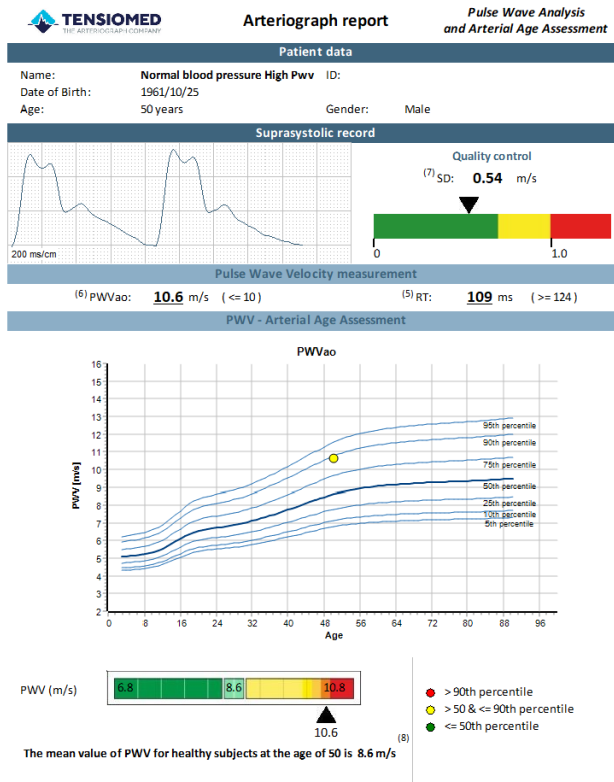
The Print preview screen can be closed by using this button.

The report printed by the Arteriograph software will contain the following:



Page 1:

- **Patient data.** The patient data are shown here including a user-defined parameter and its value, provided it is activated (Section 5.4.1). The sections for missing or undefined data will remain blank.
- **Risk profile.** The previously entered risk profile (see Section 5.4.2.2) is displayed here.
- **Medication.** The list of medications entered previously (see Section 5.4.2.2) is depicted here.
- **Measurement data.** This part contains the date and time of the examination, the name of the operator, and the mandatory patient data.
- **Suprasystolic record.** Peripheral and central hemodynamic parameters are listed here, excluding pulse wave velocity. The calculated Ankle-Brachial Index (ABI) is also depicted at this section if this option was previously activated (see Section 5.4.1). An extract of the suprasystolic pulse wave is displayed with the points of the Return Time (**RTS35**) and Dicrotic notch (Ejection Duration; **ED**) indicated on it.
- **Diastolic record.** This part contains the parameters resulting from the analysis of the pulse wave curves recorded at the diastolic pressure step. There are also two graphs showing an extract of the pulse wave curves and a single curve (the last wave if several waves are selected for analysis). The **DRA**, **SAI**, and **DAI** parameters can be obtained only if an **ED** value is available from the previous phase (Suprasystolic record).
- **Footer:**
 - **Institutional and operator data** on the left-hand side if set (Section 5.4.6.1).
 - **Manufacturer's data** complemented with the **version number of the software** on the right-hand side.



Page 2:

- **Suprasystolic record.** The first part of this page contains the quality control of the measurement. An extract of the pulse wave curves recorded on the suprasystolic pressure step is shown in a plot to facilitate observing the quality of the waveforms. The value of SD PWVao is also represented here.
- **Pulse Wave Velocity measurement.** This part displays the measured aortic pulse wave velocity and return time values.
- **PWV – Arterial Age Assessment.** The current measurement is placed in an age – PWVao graph with smoothed reference percentile curves (see Section 5.4.5.3). The point of the measurement is coloured according to the ranges in the legend of the graph. The depiction is performed in 8-year steps.
 Under the percentile graph the mean aortic PWV value with regards to the age of the currently examined patient is provided. This value derives from a database involving the data of 60.000 patients. If the measured PWV value of the patient is lower than the mean value written in this sentence, the patient is in an apparently better condition than the average, if it is equal, than their PWV is average, and if it is higher, caution, and – possibly – lifestyle change is advised. The measured PWV value is depicted on a colour scale, which facilitates this distinction further.

Note: In each case, a medical doctor’s expertise is required to evaluate the findings of the whole measurement. Do not attempt to interpret the measurement results and diagnose the patient without this knowledge!

Conclusion

Central Blood Pressure

SBPao: **133.6** mmHg



Augmentation Index

Aix aortic: **29.6** %



Pulse Wave Velocity

PWVao: **10.6** m/s



Increased cardiovascular indicators. It is advisable to seek extensive guidance from a skilled medical professional.

This examination cannot replace a medical consultation or provide a diagnosis. Elevated blood pressure and other variables can affect the parameter values.

Diagnosis

2012.02.16:

Page 3:

This page displays three bars representing the three primary parameters of arterial stiffness. Its purpose is to offer insights to the physician regarding the patient's arterial function status. If the value is represented on the green section of the respective bar, it is considered healthy, a value in a yellow section advises caution, and if it is in the red range, immediate intervention is suggested. Note that this representation does not constitute a medical examination and cannot be considered as a diagnosis! Instead, the physician shall evaluate the measurement results carefully.

The sign on the central systolic blood pressure bar is:

- in the green section, if the value of SBPao is at least 40 mmHg, less than 140 mmHg and less than the brachial systolic blood pressure value;
- in the yellow section, if the value of SBPao is higher than the brachial systole but less than 140 mmHg;
- in the red section if the value of SBPao is at least 140 mmHg (and less than 300 mmHg).

The sign on the augmentation index bar is:

- in the green section if the value of Aix is between -100% and 33%;
- in the yellow section if the value of Aix is between 33% and 43%;
- in the red section if the value of Aix is between 43% and 100%.

The sign on the pulse wave velocity bar is:

- in the green section if the value of PWVao is between 3 m/s and 9 m/s;
- in the yellow section if the value of PWVao is between 9 m/s and 10 m/s;
- in the red section if the value of PWVao is higher than 10 m/s.

Explanation of the parameters

- (1) SBPao: SBPao = aortic (central) systolic blood pressure. SBPao physiologically lower than the peripheral (brachial) SBP. SBPao is normal under 140 mmHg.
- (2) PPao: PPao = aortic (central) pulse pressure. PPao is the difference between the central systolic and diastolic pressure. PPao is normal under 50 mmHg.
- (3) Aix aortic: Aix aortic = aortic (central) augmentation index. Aix aortic is mainly determined by the peripheral arterial tone (resistance) of the small arteries and arterioles, which is influenced by endothelial NO synthesis. Aix aortic is normal under 33%.
- (4) ED: ED = Ejection (systole) duration of the left ventricle of the heart. ED is influenced by the heart rate. This parameter is not taken account in the evaluation of Arteriograph report. Normal values are described by Weissler AM, Harris LC, White GD. „Left ventricular ejection time index in man” J Appl Physiol 18 (5) 919-923; 1963.
- (5) RT: RT = return time of the aortic pulse wave. RT reflects to the characteristics of the aortic wall. The stiffer the aortic wall, the lower the RT is. RT is normal above 124 msec.
- (6) PWVao: PWVao = Pulse Wave Velocity of the aorta. PWVao is determined by the characteristics of the aortic wall (see RT). The stiffer the aortic wall, the faster the PWVao is. PWVao is normal under 10.0 m/s. Increased PWVao values are related to increased CV risk and atherosclerotic organ damage. Vascular age assessment is based on the PWVao values. Higher SBP and/or HR can increase PWVao causing enhanced lateral tension (i.e. stiffness) on the aortic wall and can lead false arterial age assessment.
- (7) SD: SD = Standard deviation of the beat to beat measured aortic pulse wave velocity values. The lower the SD the better the quality of the recording is. SD should be in the green range (0.0-0.7 m/s). Yellow (>0.7 <1.0 m/s) is still acceptable but with caution. Red range (>=1.0 m/s) cannot be accepted and the examination has to be repeated.
- (8): on the basis of approximately 60000 measurements based on internal database of the company
- (9) DRA: DRA = diastolic reflection area. The left coronary artery provides blood and oxygen supply to the left ventricle of the heart; however this artery is perfused mainly during diastole. Thus the diastolic perfusion pressure and the duration of diastole are playing determinant role in the blood supply of the left ventricle of the heart. DRA is a complex dimensionless parameter, describes the diastolic wave reflection intensity and the duration of diastole. The higher the DRA is the better the left coronary perfusion. The DRA is normal above 40.
- (10) SAI, DAI: SAI = systolic area index, DAI = diastolic area index. Pressurizing the cuff to the diastolic blood pressure volumetric signals can be obtained. The area under the curve is taken as 100%, and then it is divided into systolic (SAI) and diastolic (DAI) area and expressed as the percentage of the total (100%). In normal, resting situation with normal heart rate the SAI used to be less than 50% and the DAI more than 50%. The lower third of the DAI is under 46%, which could be considered abnormally low.
- (11) - (7): Threshold values are obtained from hard end-point follow-up study using Arteriograph. (Kahan, T. et al.: Aortic stiffness measured by a novel oscillometric method independently predicts cardiovascular morbidity and mortality: a study of 4146 subjects. ESH Congress 2013 Milan. Oral presentation, Large Arteries Session. Monday 17 June).

Page 4:

This page provides a concise description of the parameters depicted on the measurement report. This information contains the definition, normal (healthy) value range and problems regarding abnormal values of the parameters, literature references and any other important information.


Note: The report is always printed out in A4 size. It contains only the previously entered information and the results measured or calculated during the analyses.

5.4.6.3 How to send a report in PDF format

You can convert the above detailed report to PDF format by **Send PDF report** under the **File** menu and simply e-mail it. After the command is selected, the program converts the report to PDF format automatically. The generated .pdf file can be saved to a selected directory with the following file name: Tcrep_fullname_date_time.pdf, where *fullname* is the name of the patient and *date* and *time* are the date and time of the examination in the pre-set date and time format (e.g. Tcrep_TestElisabeth_26032007_07_43.pdf).

As a next step the default mailing application – if there is any – is loaded automatically with the generated .pdf file attached to a new email, and the email can be sent to any recipient.

5.4.7 Export the measurement data

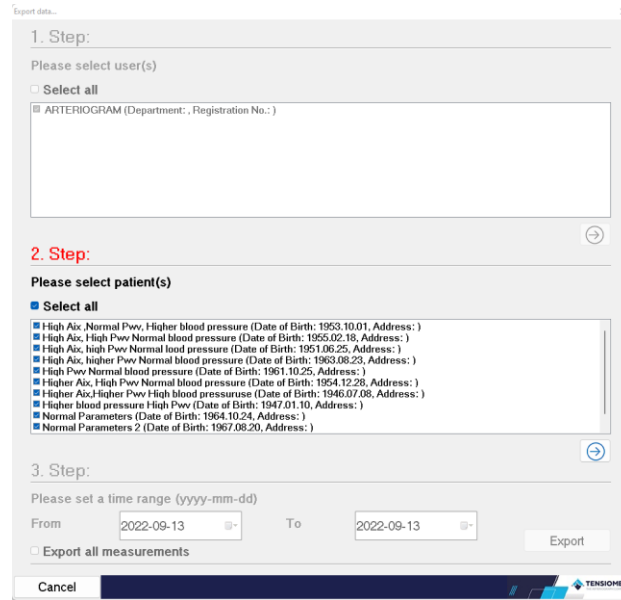
 Formerly saved measurement results (see Section 5.4.5) can be exported into a formatted text file by choosing **Export data** under the **Tools** menu or clicking the **Export data...** button on the toolbar.

- Step 1 Select a user whose patients' measurement(s) you would like to export by ticking the checkbox next to it. The **Select all** option is a quick way to select all the listed users. All the registered users are listed in this window. Continue by clicking on the first arrow.

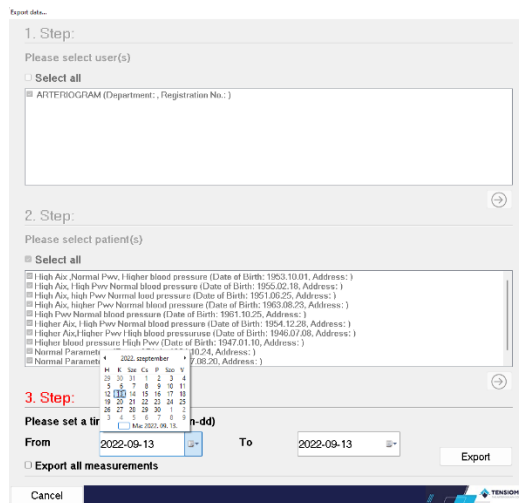
- Step 2 Select the patient(s) whose measurement(s) you would like to export by clicking on each required row. All the patients belonging to the selected user are listed here in alphabetical order of the family name.

If there is a great number of patients, a particular patient can be found by using the built-in search function. For a quick search click anywhere in the patient list and type in the initials of the given patient's family name. The built-in search is not case sensitive.

A selection of any number of the patients can be performed by ticking their respective checkboxes. The **Select all** option is a quick way to select all the listed patients. Selection is confirmed by clicking on the second arrow.



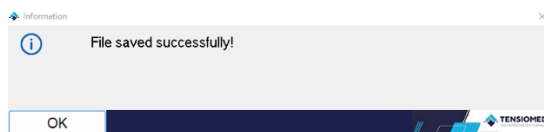
Step 3 By setting a time range here, only those measurements will be exported which were performed in the specified range. By ticking the checkbox titled **Export all measurements**, every measurement of the formerly selected patients will be exported. Click **Export** to start the process.



Step 4 The status of the export process is shown by a progress bar. In case of a large database the process can take several minutes.



Step 5 When the export is completed, the directory should be selected where the completed text file will be saved. The exported file is a tab delimited text file, which can easily be opened or imported in common spreadsheet applications (e.g. Microsoft Excel) or most of the statistical packages (e.g. SPSS, SAS)



If the operation is successful, a message window of confirmation will pop up.

5.4.8 Backup and restore the database

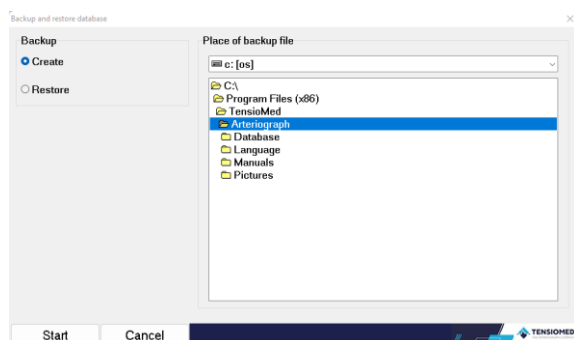
Note: The exported text file contains each measurement in a different row. Several measurements for one patient are listed under each other. If the results were not saved for a given measurement, the exported text file will only contain the patient data and the blood pressure measurement values in that row.

To protect your measurements against accidental data loss, the database should be backed up regularly. For this, use the **Backup** command under **Tools** menu.

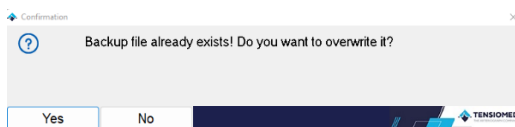
The Backup and restore dialog window appears, where you can set whether to make or to restore a database. The destination directory can also be selected.

5.4.8.1 Backup data

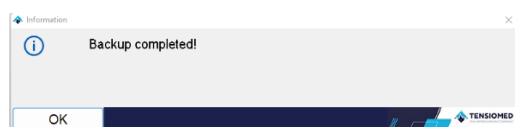
In the Backup field select **Create** to start the backup process. Also select the destination directory for the backup file.



If there is a previously saved backup file in the selected database, a confirmation window pops up for overwriting the file. If you don't want to overwrite it, press **No** and rename the previous backup file or choose another destination directory. If you approve overwriting, simply click on **Yes**. To select a backup directory, **double-click** on it. Please note that the C:\ root directory cannot be used as a backup directory!

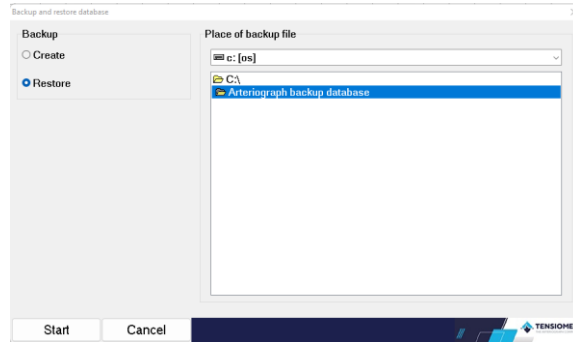


An information window pops up if the backup is successfully completed.

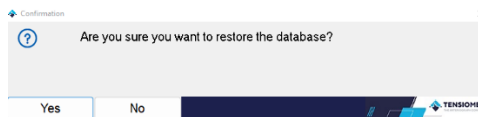


5.4.8.2 Restore data

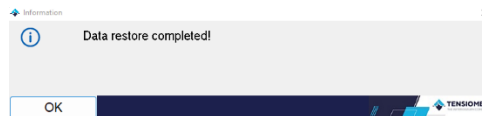
In the Backup window select **Restore** to start the restoration process. Then select the directory where the backup file created by you is located and **double-click** on it.



A confirmation window pops up for approving the restoration. To start the restoration, click on **Yes**. Pressing **No** will cancel the process.



Upon successful completion an information window can be seen.



5.4.8.3 Import previous database

If you have a previous version of Arteriograph database on your computer, the **Convert previous database and import data** command under **Tools** menu helps to convert the measurements into the new database format.

Select the patient list (.pat) file in the Regisztratumok folder under the previous installation directory (by default: C:\\Regisztratumok) and click **Open** to start the import procedure.

Note: Only a database in the original installation folder can be imported.

Note: For a large database the conversion can take several minutes. The status of the procedure is shown by a progress bar.

Successful conversion is confirmed by a pop-up window.

6. Troubleshooting

Problem	Possible causes	What to do
No communication	The device is not successfully paired with the PC	Go to Control Panel/Bluetooth Devices and check whether the device is present and paired. If not, follow the instructions of Section 5.2.
	No or low batteries in the device	Replace the batteries.
	The device was turned off	Turn on the device by pressing its button twice.
No arterial function parameters are displayed	Loose cuff	Tighten the cuff.
	Arrhythmia	The method cannot reliably assess arterial function parameters for arrhythmic patients.
	Tremor	If possible, try to terminate tremor.
No print preview	No printer has been installed to the PC.	Install a printer or use the built-in virtual printer of Windows.
The PDF report cannot be opened	Adobe Reader is not installed to the PC.	Download and install the latest version of Adobe Reader.
Database import cannot be completed	Not the proper database was selected, or the database was damaged.	Import the database by following the instructions of Section 5.4.8.3.
Cannot send e-mail successfully	No mailing application is installed to the PC.	Install a mailing application and set it as default.

Error messages

Error codes, as shown on the LCD, and their explanation are specified below. It should be noted that errors can occur due to patient movement causing artefacts in the reading. If the device cannot measure blood pressure (e.g. due to motion), the measurement will be disrupted.

Example:

Err 32

The codes of the error instances indicated by the device shall mean the following:

1	Measuring time exceeded	The device could not measure the patient's blood pressure within the pre-set time.
3	Low battery	The measurement was disrupted because of low battery.
31	Cuff missing	The cuff is not connected to the device.
32	Cuff clogged	The rubber hose of the cuff is blocked, or something is occluding the hose.
33	Air leakage	The cuff (or the device) leaks.
34	The cuff is not on the arm	While connected to the device, the cuff is not placed on the patient.
35	Measurement disrupted	For some reason (e.g. the user presses the button) the measurement is disrupted.
37	The cuff pressure has exceeded 300mmHg	During the blood pressure measurement, the cuff pressure has reached or exceeded the maximum permitted pressure of 300mmHg 's value.
90-99	Device error	The blood pressure measurement failed because of a device error which indicates the need for servicing, or the battery is low.
100	Incorrect measurement result	The calculated results cannot be considered as a proper blood pressure value, or the patient is suffering from arrhythmia.
101	Motion	The measurement conditions, e.g. the patient's movement interfere with the process of data collection.
102	No pulse detected	For unknown reasons the device does not detect the cardiac pulses.
110	Erroneous measurement result	The signals are insufficient for blood pressure calculation. (Artefacts, arrhythmia.)
111 112 113	Invalid measurement result	The calculated results cannot be considered as real blood pressure values. (The most likely reason is noisy measurement signals.)
115	Unacceptable measurement result	The pulse rate cannot be calculated or cannot be considered as a real value.

7. Technical Specification

Power supply:	Four AA long-life alkaline batteries
Protection against electric shock:	Internal supply by batteries
Grade of protection against electric shock:	BF type on patient's side
Display:	Liquid Crystal Display (LCD)
Data storage:	EEPROM
Data transmission:	Radio, Bluetooth
PC Interface:	Bluetooth Communication
PC system requirements:	Windows 10 or 11 OS installed
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
Dimensions:	116 x 94 x 47mm
Weight (incl. batteries):	250g
Blood pressure measuring method:	Oscillometric
Sampling frequency:	200Hz
Blood pressure (BP) and heart rate (HR) measuring range:	BP 30 – 280 mmHg; HR 40 – 200 / min
Static accuracy:	± 3mmHg or ±2% of the measured value (Stability: 18 months)
Measurement accuracy:	Systolic: 91 (91%) out of 99 comparative checks fall within 5 mmHg, For 33 patients out of 33, 2 of 3 comparative checks fall within 5 mmHg, 0 of 33 patients did not have a value within 5 mmHg after 3 measurements. Diastolic: 97 (98%) out of 99 comparative checks fall within 5 mmHg, For 33 patients out of 33, 2 of 3 comparative checks within 5 mmHg, 0 of 33 patients did not have a value within 5 mmHg after 3 measurements. Average deviation from auscultatory measurements (Korotkov sounds): (systolic/diastolic): 0.4/-0.3 mmHg Standard deviation (systolic/diastolic): 2.7/2.3 mmHg
Pressure sensor:	Piezo-resistive
Inflation:	Automatic motor-driven pump
Safety:	Maximum cuff pressure: 300 mmHg; Maximum measurement time: 180 seconds
Deflation:	Automatic, stepwise


7.1 Electromagnetic compatibility

Electromagnetic emissions		
The Arteriograph device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11:2009 +A1:2010	Group 1	The Arteriograph 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 Arteriograph 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 Arteriograph device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 transients/bursts IEC 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	-
Surges 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	30 A/m	Test level: 30 A/m Test time: 60 s	If image distortion occurs, it may be necessary to position the Arteriograph 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 Arteriograph device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 Arteriograph device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E} * \sqrt{P} = 2 * \sqrt{P}$
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 %	$d = \frac{6}{E} * \sqrt{P} = 2 * \sqrt{P}$ where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, <i>E</i> is the immunity test level and <i>d</i> 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 Arteriograph device is used, exceeds the applicable RF compliance level above, the 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 Arteriograph 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 Arteriograph device

The Arteriograph device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent *electromagnetic* interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Arteriograph 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	80 MHz – 800 MHz	800 MHz – 2,7 GHz
	d= 2√P	d= 2√P	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.

7.2 Use Specification

Intended medical indication	Non-invasive determination of brachial blood pressure, heart rate, and central hemodynamic parameters in a medical office. Only a medical professional is allowed to evaluate the measurement results! Assessing the hemodynamic parameters affected by various factors of the patients' arterial circulation. The contraindications are listed in sections 1.1. and 1.5.
Intended patient population	Cannot be used on patients under 3 years of age. Clinically validated on a patient population above 3 years of age.
Intended part of the body or type of tissue applied to or interacted with	The cuff interacts with the skin surface of the upper arm or the ankle and exerts pressure on it when the device is in use.
Intended user profile	Physician, medical staff.
Use environment	Medical outpatient, medical diagnosis where applicable. See sections 1.1. and 1.5. for details.
Operating principle	Oscillometric method



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