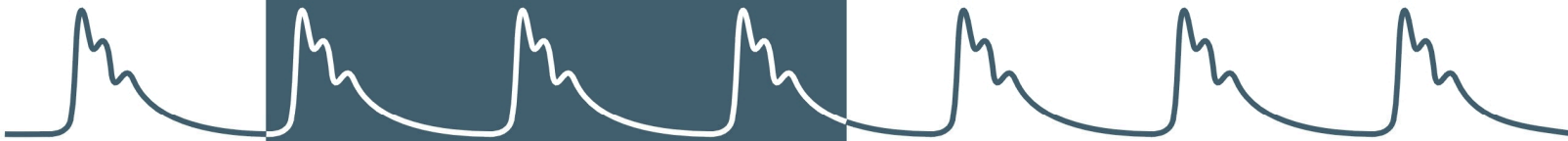


TENSIO MED®



ARTERIOGraph™

Instruction for use

Arteriograph (version: TL2)
Arteriograph Software

CE 0197

TENSIO MED®

TensioMed Arteriograph-02 v7-00

Revised: 03-12-2021

TENSIO**MED**®

ARTERIO**Graph**™

Arteriograph and 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 2000 / XP / Vista / 7 / 8 / 10 Operating Systems.

If the operator is not familiar with Windows operations, please refer to the On-line Help of Windows or the Windows User Manual.

Arteriograph is an unregistered trademark of TensioMed Ltd.

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Head office and service:

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Budapest H-1181

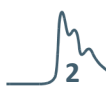
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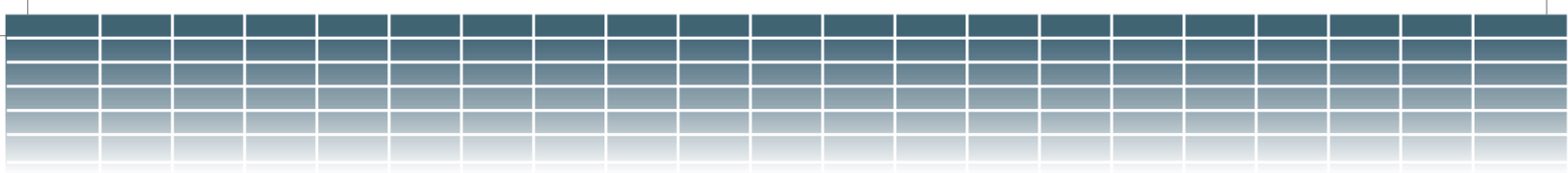
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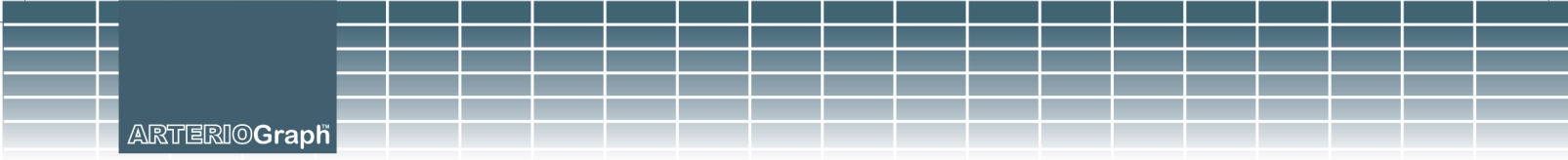




Contents

1	Introduction and the determination of the intended use of the device.....	5
1.1	Preface and the determination of the intended use of the device	5
1.2	Contents of the manual.....	5
1.3	General information	6
1.4	Guarantee.....	7
1.5	Warnings and precautions	8
2	The TensioMed Arteriograph device.....	10
2.1	The device at a glance	10
2.2	The accessories of the Device	11
2.3	Installing the Device	11
2.4	Operation instructions	12
2.5	System (Bluetooth communication) setup.....	12
3	The software	13
3.1	TensioMed Arteriograph Software installation and setup	13
3.1.1	Preliminary information about the software.....	13
3.1.2	Minimum system requirements	13
3.1.3	Software Installation.....	14
3.2	The software at a glance	16
3.2.1	The Menu of the Program.....	17
3.2.2	The Toolbar of the Program.....	18
3.2.3	The examinations window.....	18
3.2.4	The results block.....	18
3.2.5	Patient details field	18
3.2.6	The measurement data window.....	18
3.3	First step – Register a user	19
4	Performing a single blood pressure measurement.....	20
4.2	Performing the measurement.....	20
4.3	Acoustic signals	21
5	Performing pulse wave recording and analysis.....	22
5.1	Hemodynamic parameters measured by the Arteriograph	22
5.2	System setup	23
5.3	Patient preparation	23
5.4	Performing the measurement.....	26
5.4.1	Device and measurement setup	26
5.4.2	Select a patient	29
5.4.2.1	How to select an existing patient.....	29
5.4.2.1.1	How to modify a patient's data.....	29
5.4.2.1.2	How to search for a patient	29
5.4.2.2	How to enter a new patient's data	30
5.4.3	Medical Examination with TensioMed Arteriograph.....	31
5.4.4	Quality control of the measurement	32
5.4.4.1	Quality control index: the SD PWVao	33
5.4.4.2	Quality control by visual inspection	33
5.4.5	How to analyse the data	36
5.4.5.1	Tools for visual inspection.....	40
5.4.5.2	Oscillation amplitudes during blood pressure measurement.....	41
5.4.5.3	Vascular age assessment.....	42
5.4.6	The measurement Report.....	42
5.4.6.1	Edit the Report	43
5.4.6.2	Print the Report	44
5.4.6.3	How to send a Report in PDF format	47
5.4.7	Export the measurement data.....	47
5.4.8	Backup and restore the database	50
5.4.8.1	Backup data.....	50





- 5.4.8.2 Restore data51
 - 5.4.8.3 Import previous database51
- 6 Troubleshooting52
- 7 Technical Specification54
 - 7.1 Electromagnetic compatibility55
 - 7.2 Use Specification57

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

1.1 Preface and the 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 in patients where knowledge of aortic blood pressure and other central arterial functional parameters is desired, but the physician considers that the risk of measurement with a catheter or other invasive method outweighs the benefits of knowledge of the parameters.

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

The 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 the Arteriograph. Do not use the device on patients if **high frequency electrosurgical equipment** is applied on them.

If the patient is in a **hyperbaric oxygen chamber**, the Arteriograph should not be used.

If the patient has a **skin disease or wound on the upper arm** where the cuff is planned to be placed, the arteriograph should not be performed.

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

With regard to 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 arterial functions (PWVao, Aix-ao, SBPao, RT, SAI, DAI, DRA) in methodological guidelines are currently not yet available, although a large number of 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 national languages.*

1.2 Contents of the manual

This manual helps you in setting up and starting to use the Arteriograph (version: TL2) device as well as installing and setting up 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 principle of Arteriograph's operation is based on a patented, innovative solution. The cuff placed on the upper arm first measures the patient's blood pressure using an oscillometric method. After a few seconds, the instrument will re-inflate the cuff to the currently measured diastolic value and then to the so-called suprasystolic pressure, in both cases for 4-10 seconds (adjustable length). Then the instrument deflates the cuff, i.e. the measurement is completed. The whole process takes up to 2 minutes. During the measurement described above, the instrument continuously transmits signals to the program running on the computer, where oscillometric curves generated by pulsation of the vascular wall can be observed in real-time display on the screen. Upon completion of the measurement, the algorithm running in the computer program analyses the signals 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 downloaded into 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 maintained at the manufacturer's service every second year.
- 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:

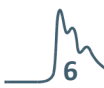
- a., Alcohol based disinfectant
- b., Isopropanol (70%)

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

Please avoid disinfecting the cuff bladder and connected rubber tube. Before the disinfection, take the bladder and the tube carefully out of the cuff sleeve. The bladder and tube may be damaged by disinfectants. Do not place the cuff sleeve in the disinfectant material.

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. The



cuff sleeve 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 must be handled, stored, packaged, protected and shipped in compliance with the general quality requirements.
- The device meets the requirements of next standards:
 - EN 1060-1:1995+A2:2009 Non-invasive sphygmomanometers – Part 1: General requirements
 - ISO 81060-2:2013 Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type



Attention! Federal Law restricts this device to be used by or on the order of a physician, or other licensed practitioner (US only).

1.4 Guarantee

TensioMed Ltd. offers a 2-year warranty for the device. Any repair and device calibration within or beyond the warranty period are performed by TensioMed Ltd. in the service station of the company (97. Kossuth Lajos str. Budapest H-1181)

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 2 years for examination.

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). Please do not try to repair 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 has an integrated safety mechanism, which prevents the cuff pressure to exceed 300 mmHg. If however the inflation continues above this value or the pressurization lasts too long, unplug the tube of the cuff from the device and remove the cuff from the subject.

Too frequent or too long pressurization by the cuff can cause blood flow interference. Ensure that measurements do not result in prolonged 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 suffering from coagulation disorders, because the compression of the arm by the cuff may cause suffusion.

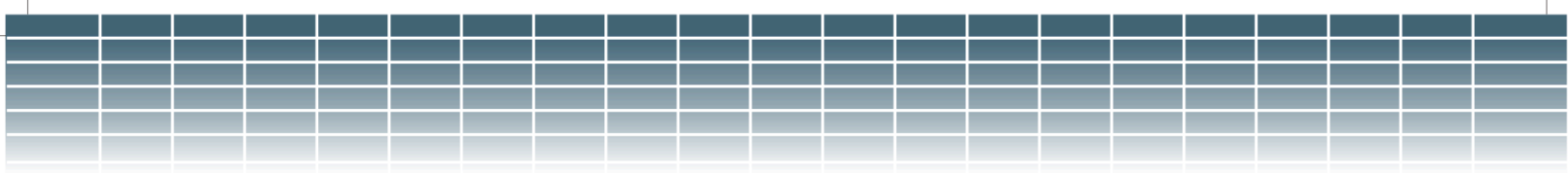
If a patient has previously undergone a vascular surgery (such as a shunt between the artery and the vein) and / or a permanent or temporary cannula has been inserted into the vein, or into the artery, for the administration of intravenous drug, do not place the blood pressure cuff on this arm, but perform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

If an extensive mastectomy operation was performed on a patient before 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! Cannot be used on persons below 3 years of age!

In the case of an active skin disorder affecting the arm, or in case of any kind of inflammation or wound existing on the arm please use for the measurement the intact arm. In order 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.

There is no contraindication to the use of the Arteriograph instrument on pregnant women. However, the user is reminded that the clinical validation of blood pressure measurement has not yet done in pre-eclamptic patients. Despite this, the prognostic significance of arterial function parameters provided by Arteriograph in the case of pregnant women has been demonstrated by an independent clinical trial involving over 6,000 patients (Ultrasound Obstet Gynecol. 2012 Jul; 40 (1): 28-34).



Device use

The user of the Arteriograph instrument is expected to be able to read, understand and learn the contents of the user manual, to a minimum. When using software (SW), it is a physical requirement to see and understand the messages and inscriptions of SW. It is also a minimum requirement for the user to physically be able to fit the cuff, the recess of the upper edge of the sternum and the distance between the upper edge of the pubic bone and the measurement of the arm circumference with a measuring tape, and to operate the computer program. For the proper execution of the Arteriograph measurement, there is no need for special and / or educational qualifications.

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 can lead to erroneous measurement results.

Confirm blood pressure measurement with auscultation when erroneous results are suspected.

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

Do not use the device when it is exposed to mechanical vibration (e.g. in vehicles).

Prevent the device and its accessories to be exposed to direct sunlight, to get in contact with 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.

Do not connect the device to a computer network, use it only with the computer you installed the user software on! Else an „Access violation“ error will occur.

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

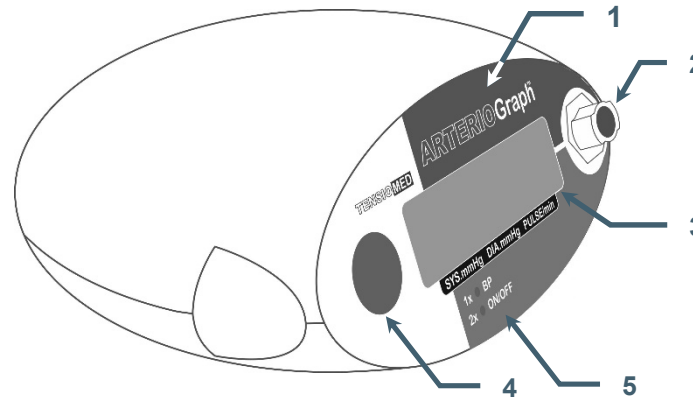
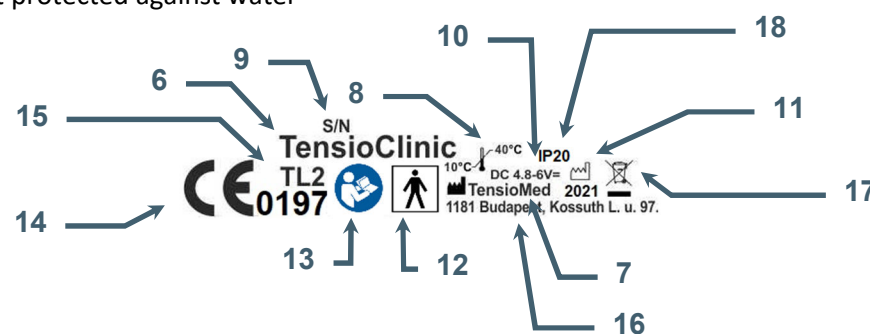
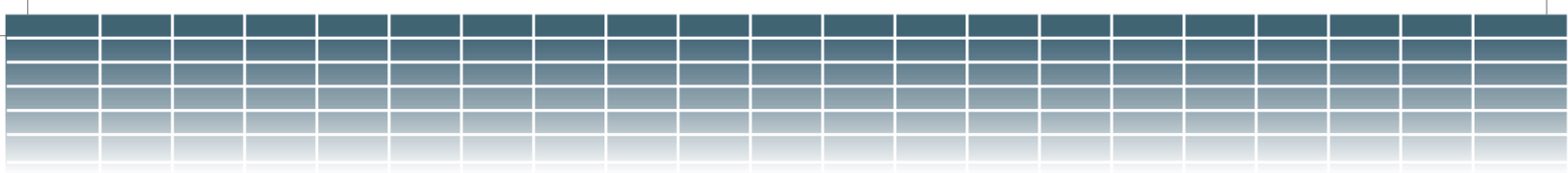


Figure 1

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 with EU requirements
15. Type ID of the Device
16. Head office of Manufacturer
17. The permanently placed in unused equipment must be collected in order to get more efficient reuse and recycling , as well as harmful effects on human health and for the environment of the ingredients are selectively
18. Level of protection against any liquid or grainy material filtering into the device (IP N₁N₂)
N₁=2: Protected against solid foreign objects of 12,5mm and greater
N₂=0: Not protected against water





2.2 The accessories of the Device

Arteriograph has the following accessories:

- Three cuffs of different sizes (see below)
- Arteriograph Software installation CD and flash drive with Instruction for use
- Instruction for use

The cuff is the patient's part 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	Bladder dimensions	Sleeve dimensions	Arm circumference range
Cuff: S	20 × 8 cm	41,5 × 10 cm	20 – 24 cm
Cuff: M	23 × 11,5 cm	57 × 14 cm	24 – 32 cm
Cuff: L	28 x 11,5 cm	64 x 14 cm	32 – 38 cm

The manufacturer of the cuffs:

ERKA. Kallmeyer Medizintechnik GmbH & Co. KG
Im Farchet 15, 83646 Bad Tölz, Germany

2.3 Installing the Device

Arteriograph is a battery operated device.

- Insert 4 durable alkaline AA batteries into the Device with taking care of the right polarity (see Figure 3)
- Or insert 4 AA sized rechargeable Ni-MH or NiCd batteries as per the above instruction. (Please note that new batteries must be pre-charged.)
 - For problem-free operation minimum 1,500 mAh chargeable Ni-MH or NiCd batteries are recommended.



Figure 3

Note: The clock circuits of the Device are fed by integrated NiCd HA 35 battery cells, 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 period of time, 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 both rechargeable and 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 for alkaline batteries and between 4.8 V and 4.6 V for rechargeable batteries.
- If the voltage drops below 4.4V, the batteries must be replaced. A warning symbol of low battery appears on the LCD.
- The Device is ready for operation if the current PC time appears on the LCD.

5.6V

LOW Batt

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2.4 Operation instructions

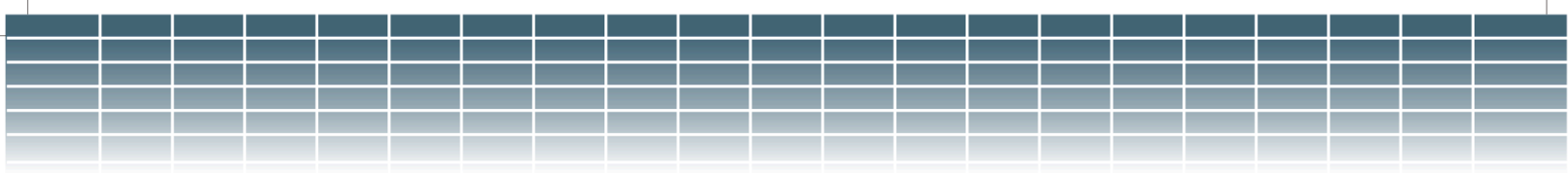
There is a single push button available for operating the Device (Section 2.1). The user can use the only push button for issuing a total of two commands.

1. **By pressing** the button shortly manual blood pressure measuring 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 initialized 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 (Arteriograph SW) is a Windows-based software. The common Windows mouse operations are to be used in the program (left single-click, double click, drag, etc.).

Button and command names ending in ... indicate that a dialog window will open upon clicking on those items.

Arteriograph SW allows you to perform arterial function measurement, to print and share the measurement report and to modify the measurement settings.

3.1.2 Minimum system requirements

- Pentium IV PC, 256MB memory, 2GB available HDD capacity, CDROM, 1024*768 resolution,
- Windows 2000 operating system with Service Pack 4, Windows XP with Service Pack 2, Windows Vista, Windows 7, Windows 8 or 8.1, Windows 10 installed,
- Active Bluetooth v2.0 port.

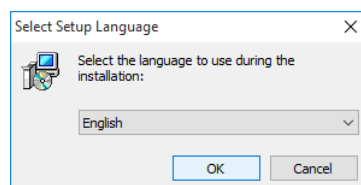
Although the Program can start in a less powerful environment, in that case we cannot take responsibility for its fast and reliable operation.

3.1.3 Software Installation

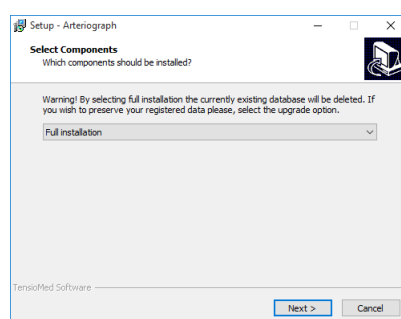
For installing the Arteriograph SW on the computer the user must have administrator privileges. After the installation is completed, please visit our website (www.tensio-med.com) for the latest information on software upgrades.

- Step 1 Insert the CD into the CD tray of your PC. The installation procedure will start automatically. In case it does not, start the installation by double-clicking the **setup.exe** file on the disc with use of a file manager program.
Should a security warning pop up, simply press **Yes** to start the installation

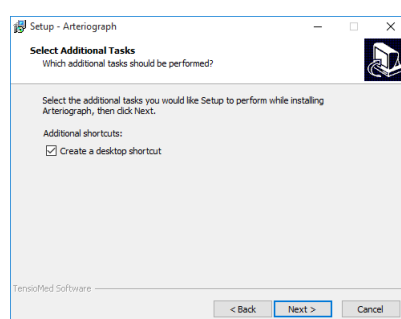
- Step 2 To start the Setup Wizard, choose a preferred language for installation and click OK.

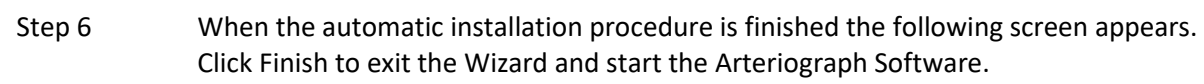
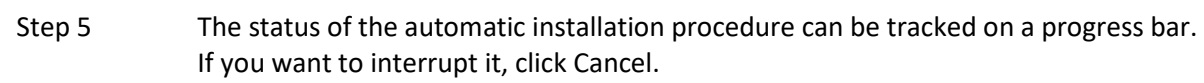


- Step 3 Select the components to be installed from the drop-down list. The type of installation can either be Full or Upgrade.
When the preferred component is selected, click Next.



- 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.





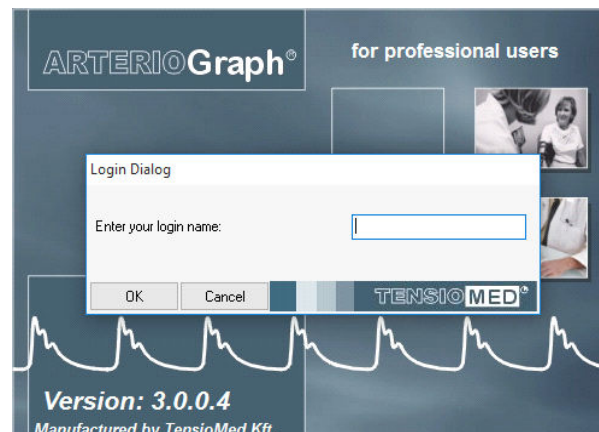
3.2 The software at a glance

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



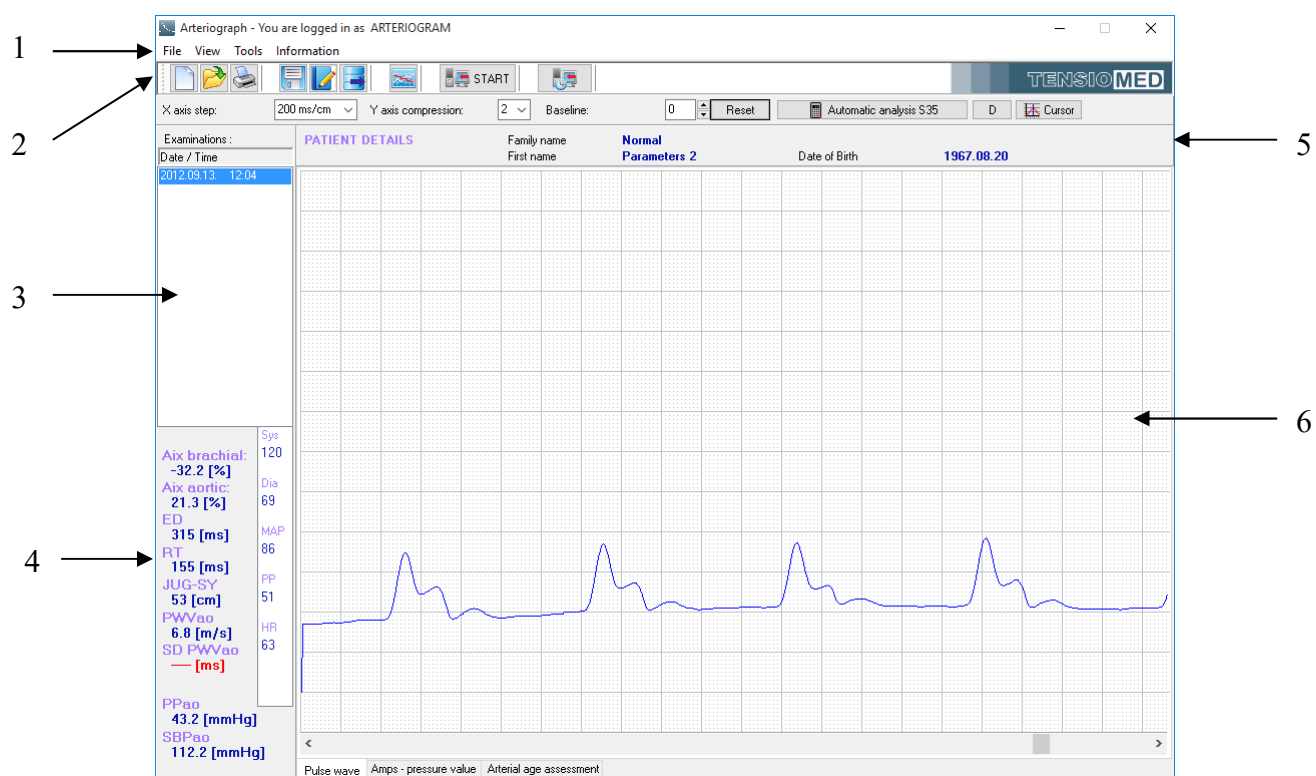
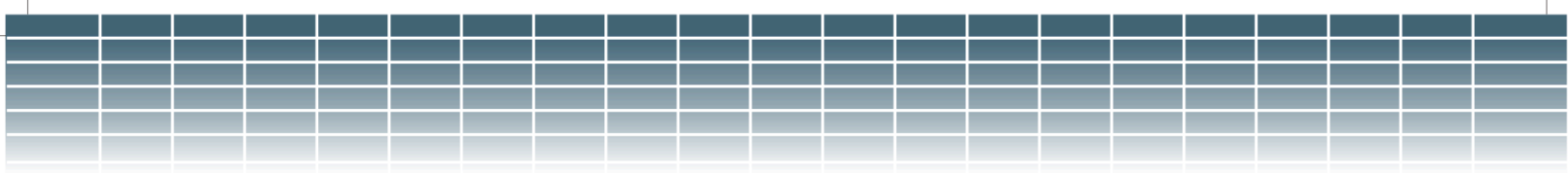
A splash screen appears along with a login dialog window.

When started for the first time, simply press OK and the Program logs in the user with the default “ARTERIOGRAM” login name. On every login after that, however, the user name must be specified.



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

1. Menu bar
2. Toolbar
3. Examinations window
4. Results field
5. Patient details field
6. Data window

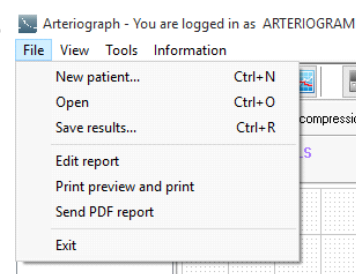


3.2.1 The Menu of the Program

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

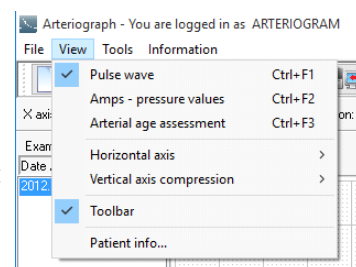
The **File** Menu

The basic functions of Arteriograph SW can be accessed through the **File** menu. You can enter new patients, open, edit or delete existing database records, save the result of an analysis; furthermore edit, print and send medical reports, as well as log out and exit.



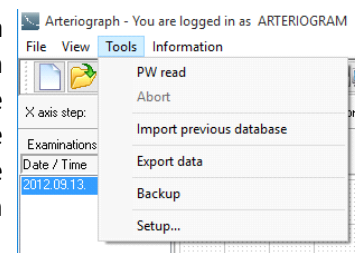
The **View** Menu

The **View** Menu enables you to choose to display the pulse waves recorded or the maximum amplitudes of the oscillatory signals at each cuff pressure step (deflated stepwise with 10 mmHg) during blood pressure measurement. Furthermore you can set the scale both horizontally and vertically, hide the Toolbar, and get information about the currently studied patient.



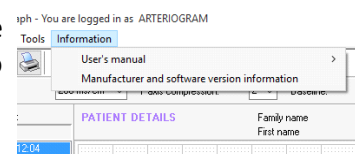
The **Tools** Menu

The **Tools** Menu enables you to start automatic pulse wave data collection by means of the Arteriograph Device, as well as 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

The most important information about the manufacturer and the software can be accessed through the **Information** menu. The menu also includes this Instruction for use (User's manual).



3.2.2 The Toolbar of the Program

The toolbar can be found under the menu bar and contains icons, which allow direct access to the major functions of the program. The Toolbar can be displayed or hidden by the **Toolbar** command of the **View** Menu.

3.2.3 The examinations window

All the previous – if there are any – examinations of the selected patient are listed here by the date and time of recording.

3.2.4 The results block

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

3.2.5 Patient details field

The name and date of birth of the patient are displayed in this field.

3.2.6 The measurement data window

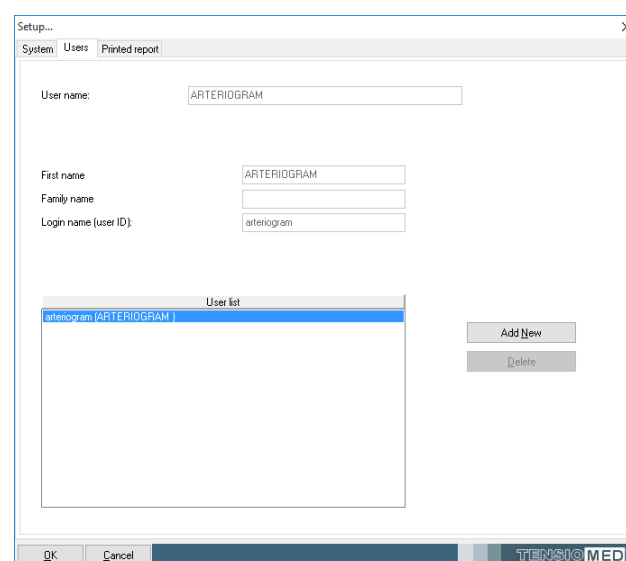
During the measurement the data are displayed here real-time in the form of non-calibrated pressure curves (oscillations) as recorded by the device. The recorded and saved pressure waves can be opened and displayed at any later time. The User can also select to display the amplitudes of the oscillometric curves throughout the blood pressure measurement phase, or 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 users with different groups of patients, it may be necessary that users can access their own respective patients' data only after login. To this end a new user will have to register in the database by specifying the name and login. Arteriograph SW can be used with the default login of "ARTERIOGRAM"; it is, however highly recommended to create and use your own user login.

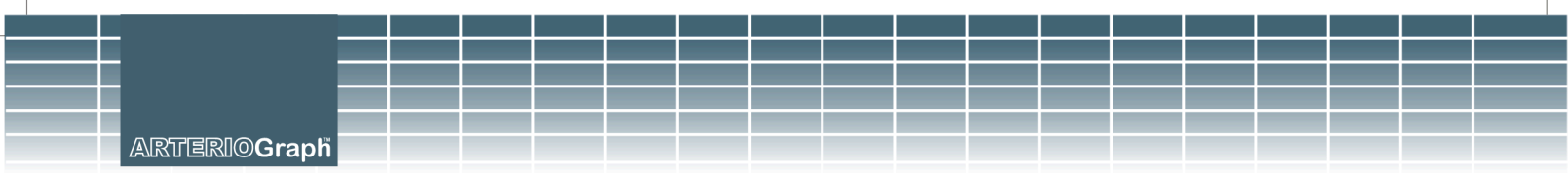
Registration of a new user

To register a new user, open the **Options...** window under the **Tools** menu and select the **Users** tab. To enter a new user click on **Add New** and then enter the first and family names of the user and specify a login name (user ID). Click **Add** to register the new user in the database or click **Cancel** to interrupt the registration. The new user can log in with the login name specified. **Note! The registered users' data cannot be edited.**



How to delete registered users

To delete registered users, select **Options...** under **Tools** and click on the **Users** tab in the pop-up window. The **Delete** button can be used for deleting a pre-selected item from the users list. In case the list contains only one user, the Delete function will not be available.



4. Performing a single blood pressure measurement

4.1 Performing Arteriograph measurement

To operate Arteriograph first install the device (see Section 2.3). There is a single push button (Section 2.1) available for operating the Device. The measured values and the status of the Device are shown on the LCD.

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

D 09-39

By pressing the button shortly manual blood pressure measuring will start.

Note: In this case the Device performs blood pressure measurement without arterial function (e.g. PWVao, Aix) evaluation.

By doing so, the current time will disappear from the display and then:

- The LCD test pattern is displayed,
- The supply voltage is checked

88888888

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 deflation an arrowhead pointing downwards indicates the procedure.

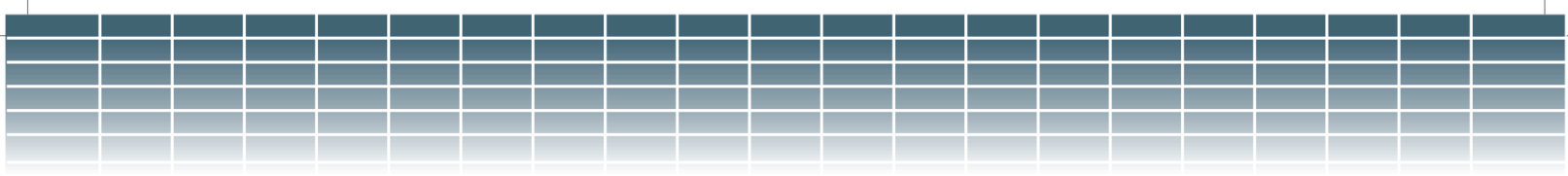
▼ 69

When measurement is completed, the Device displays the systolic and diastolic values,

128/96

and then the heart rate.

PUL 68



The measuring process can be disrupted any time by a single press on the button. The text “OFF” will appear and remain visible for about 5 seconds on the display. Thereafter the time is displayed again, which indicates the ready-to-operate status for another manual or programmed measurement.

OFF

4.2 Acoustic signals

When the Device is active, a gentle acoustic signal is emitted when its button is pressed down.

5. Performing pulse wave recording and analysis

Pulse wave registration can only be initialized by Arteriograph SW that is running on a PC with wireless Bluetooth data transmission link to the Device (in this case the button of the device should not be used)!

The oscillatory signals recorded during the whole measuring process are displayed real-time on the PC 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)

As calculated from the brachial systolic and diastolic blood pressure.

$MAP = \text{diastolic blood pressure} + (\text{systolic} - \text{diastolic blood pressure})/3$

PP – Brachial Pulse Pressure (mmHg)

PP is the difference between the systolic and diastolic blood pressure 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 late (backward) systolic wave (P_2) and the early (forward) systolic wave (P_1) over the pulse pressure (PP) and multiplied with 100

$Aix = (P_2 - P_1)/PP * 100$

Aix aortic – central augmentation index (%)

Calculated on the basis of a very strong ($R > 0.9$) linear relationship 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-span between the opening and closing of the aortic valves.

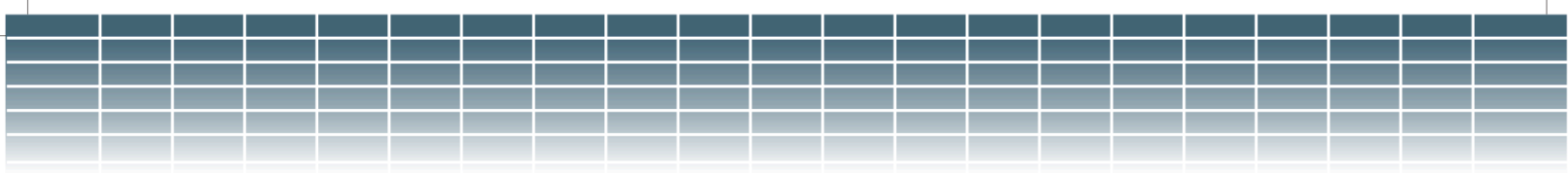
RT – Return time (ms)

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 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 measured transit time ($RT/2$).



SD PWVao (m/s)

A parameter informing about the quality of the measurement. The PWVao is calculated from each pulse recorded and the standard deviation is featured. For more details, see Section 5.4.4.1.

SBPao – central systolic blood pressure (mmHg)

Calculated on the basis of the physiological relationship between diastolic BP, mean arterial BP, peripheral and central Aix and central SBP.

PPao – central pulse pressure (mmHg)

The difference between aortic systolic and diastolic BP values.

DRA - Diastolic Reflection Area (Dimensionless index)

DRA provides information about the quality of diastolic filling in the coronary arteries, taking into consideration the duration of the diastole and the area between the expected (theoretical) diastolic pressure curve without reflection and the truly measured diastolic curve with reflection. (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.

5.2 System setup

After installation, connect Arteriograph to the PC by following the instructions of the enclosed Bluetooth Operation manual. The passkey of the device is 0000.

The device should not be farther than 10 metres from the PC for optimal operation.



Attention! Transmission-inhibiting 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.

When an active Bluetooth device (e.g. a PC) tries to add Arteriograph the sign shown on the right appears on the LCD. No actual data transmission takes place yet. Adding Arteriograph is only possible by entering its passkey (see above).

BLUELINK

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

5.3 Patient preparation

We have extensive experience with the application of Arteriograph in the 3-95 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 of adequate quality for

evaluation in case of overweight, thick-arm patients, the examination can be carried out without any problems. However, we would like to note that the use of Arteriograph may be limited in the case of patients with extreme overweight, that is, we cannot expect to achieve a successful measurement in all patients.

There is no special height limit when using the instrument.

There are no obstacles to serial repetition of Arteriograph measurements, even at intervals of 2-3 minutes. However, the investigator should carefully consider that the patient is unavoidably accompanied by a degree of inconvenience with multiple measurements, therefore the value of the information obtained from the series measurements and the said inconvenience for the patient should be proportional to each other.

Our studies of large-scale patients so far show that a single measurement of compliance with the above requirements is sufficient to judge the patient's cardiovascular prognosis during screening tests. However, it gives greater reliability if we take the average of 3 consecutive measurements.

Wrap the cuff around the dominant upper arm. When doing this procedure, please consider the followings:

- Use the cuff suggested by the software (see Section 5.4.2)
- Make sure that the cuff is tightened properly, without causing harm to the patient. The cuff should fit the patient's arm evenly. Tightness is sufficient if your finger cannot or can only hardly be inserted under the cuff.
- Make sure that the patient's skin is not pinched by the cuff.

According to the guidelines for measuring arterial function routinely the supine position is recommended for measurements. In case the examination is performed while the patient is seated, indicate this fact in the "Comment" field of the SW when the patient's data are entered.

Note: If the cuff is too loose or big, the SW does not provide measurement results and gives 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 in the cuff.

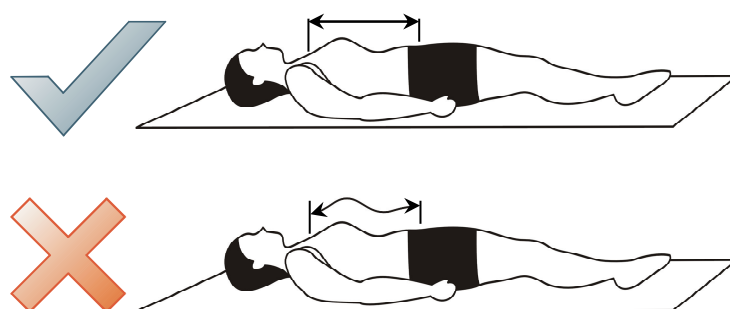
It is recommended that the patient should be in a supine position during measurement. If the patient is in a sitting position during the test, record it in the "Comment" field of the software when entering the patient's data. The patient in this case shall sit comfortably, with both feet flat on the 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 hemodynamically.

- 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 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 by ensuring that it isn't compressed or kinked.

- Connect the hose of the cuff to the air connector of the Device. For this, push the plug on the hose into the air connector of the device and 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 use of the supplied tape measure.

Note: The suprasternal notch (jugulum) – pubic bone (symphysis) distance should be measured in a straight line. Measuring on the body surface can lead to overestimation (e.g. in case of obese patients).



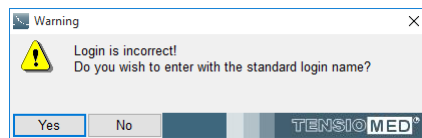
- Ensure optimal measuring conditions:
 - Speaking, muscle movements, especially the movement of arm muscles must be avoided as these activities significantly increase the measuring time, may result in measurement failure or may reduce the precision rate thereof. Muscle movements (tremor) distort the form of the measured pulse wave and render its evaluation impossible.
 - Within 3 hours before the examination the patient should not consume a greater amount of food, drink coffee or smoke. However, the patient should not be measured in fasting condition, either. A light meal is suggested within 2-3 hours before examination. Additionally, within 10 hours before the examination alcohol consumption should be avoided.
 - 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 a few minutes' intervals or the examination should be repeated in 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 separately in location and in 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. Log in to the software with the previously specified user name (see Section 3.3). (When started for the first time, the Program logs in the user with the default “ARTERIOGRAM” login name. On every login after that, however, the user name must be specified.)

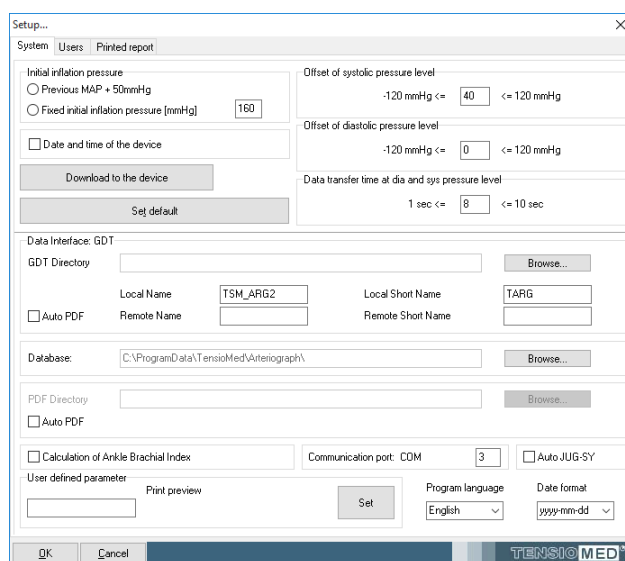
In case a wrong or non-existent user name is given, the Program will offer the default name.



5.4.1 Device and measurement setup

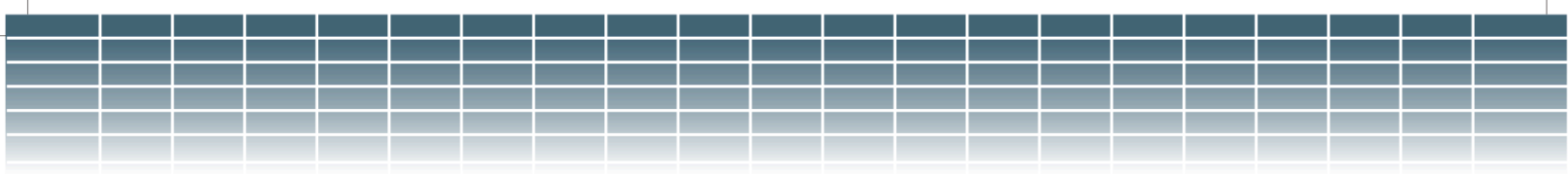
Before starting the measurement changing or checking setup parameters may be needed.

For setting up the Device select **Options...** under the **Tools** menu.



In the pop-up window the following parameters can be set in 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. In this latter case 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 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.
- **Offset of diastolic pressure level** determines the value which is added to the measured diastolic pressure in order to obtain the pressure step where the Device will record diastolic



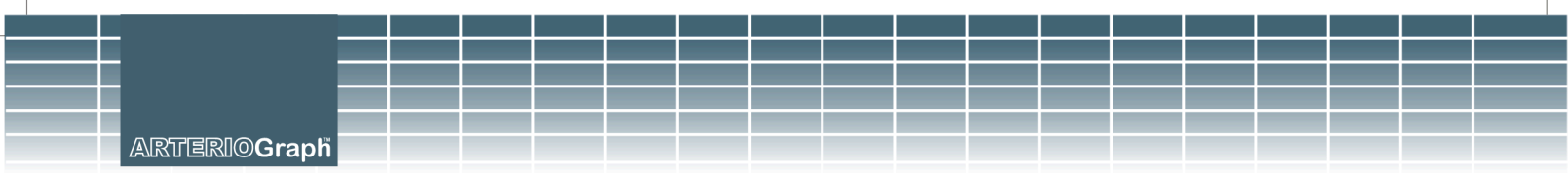
pulse wave data (volume curve). Zero (0) is the default setting, which means that data will be collected at the pressure step corresponding to the measured diastolic value. Diagnostic examinations should not deviate from this value.

- **Data transfer time at dia (diastolic) and sys (systolic) pressure level** determines the time-span (in seconds) of pulse wave data collection at the above-specified pressure levels. The default value is 8 sec. Diagnostic examinations may deviate from this value in the 7-10 sec 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 route, 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 - writable - directory path where the software will automatically save the test report in pdf format.
- **Calculation of Ankle Brachial Index**; if selected, Ankle-Brachial Index is calculated. For this the ankle systolic blood pressure has to be measured before 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 automatic port search. The proper port number can be checked under Control Panel -> Bluetooth devices. If this field is left blank, the software performs an automatic port search when starting the measurement. This process may take up to one minute.
- **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 on the basis of the patient's height, based on a large database.
- **User defined parameter**; One new parameter can be added to the patient's data-set 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: A new parameter can be added to a patient's data only once and cannot be modified or deleted later. The new parameter will automatically be added to all the patients in the database. After setting it into either a new patient's data or an existing patient's data, the patient characteristics will feature this newly specified parameter, as well.

Non-Device-specific settings:





- **Program language;** the language of the Arteriograph SW can be selected. The change only takes place upon the next SW start.
- **Date format;** one of the following date formats can be selected: Year-month-day, day-month-year, and month-day-year.

Default settings can be restored by clicking on **Default Settings**. The settings must be downloaded into the Device to take effect. For this use the **Downloading into 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

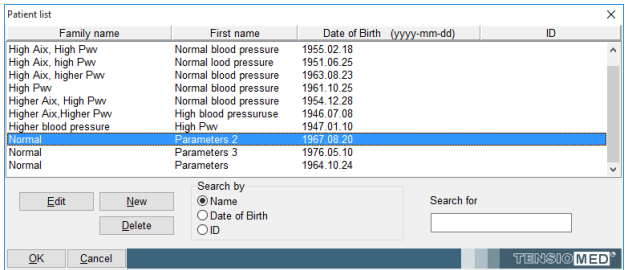
Successful data download will be confirmed on the PC.

Note: The downloaded settings into the device cannot be cancelled. They can be overwritten through re-programming.

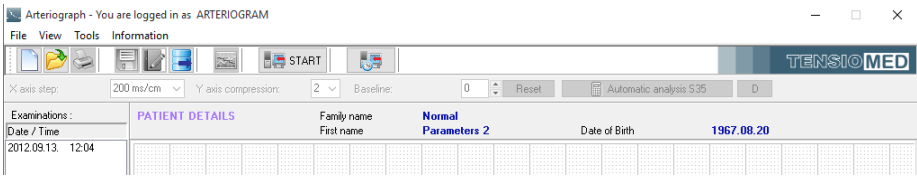
5.4.2 Select a patient

5.4.2.1 How to select an existing patient

 After logging in 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 user logged in. 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.



5.4.2.1.1 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 Patients’ List) and press **Edit**. Click on **OK** to save the modified data.

5.4.2.1.2 How to search for a patient

In case there is a great number of patients, a particular patient can be found by using the search function of the software.
For a quick search click anywhere in the patient list and type in the initials of the family name of the given patient. The quick search is not case sensitive.
An advanced search can be done by name or date of birth with use of the “Search for” 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 for not necessarily including the initial of the name.

5.4.2.2 How to enter a new patient's data



If you want to enter 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 entering a new patient only the date of birth, the height, the patient's jugulum – symphysis (JUG-SY) distance and the upper arm circumference are required to be filled out. The jugulum – symphysis distance and the upper arm circumference can be measured by means of the tape measure provided as an accessory (see Section 5.3). The former data is necessary for calculating the pulse wave velocity while the latter 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 good 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 on 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 family history, duration and frequency of smoking, etc.

New patient...

Demographics

ID

Family name

First name

Date of Birth Region

Postal code City

Country code

Address

Telephone Mobile phone

E-mail

Comment

Characteristic

Height cm Weight kg BMI 0,00

Arm circumference cm ☐ Left ☐ Right

Suggested cuff type:

JUG-SY cm Gender ☐ Male ☐ Female Smoker ☐ No ☐ Yes

Cholesterol mmol/l

User defined parameter

Risk profile

Medication

OK Cancel TENSIO MED®

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

Repeated measurements

Length of test: 15 min

Frequency: 5 min

☒ Save results automatically

Number of remaining measurements: 3

Start Stop

Cancel TENSIO MED

When starting a measurement a confirmation window will pop up with some important measurement information. If the listed data are correct, press **Yes** to start the measurement process. If these data need to be modified, press **No** and edit the patient's characteristics (see Section 5.4.2.1.1)

Confirmation

Arm circumference: 25 cm
Suggested cuff type: M (bls: 23.5x11cm)
Operator's name: ARTERIOGRAM

Yes No TENSIO MED

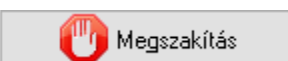
The measurement process starts with the SW connecting to the Arteriograph device. The scanning of the active ports and the communication process can be tracked on the monitor. While this communication is in progress, "CONNECT" (See Section 5.4.1) will appear on the LCD of the Device.

After a short time measurement will start automatically by performing a blood pressure measurement in the first phase. During measurement the recorded pulse wave curves can be tracked on the screen. In the second phase the pulse wave recording for pulse waveform analysis is performed.

- First the Device will inflate back to the diastolic pressure level and register the pulse waves for a previously determined duration (8 sec by default).
- Second, the Device inflates further to the suprasystolic pressure level (by default to the measured systolic value + 35mmHg) occluding the brachial artery completely in this way and registers the pulse waves for a previously determined duration (8 sec 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 PC, as well. The SW displays the followings: systolic and diastolic blood pressure values, heart rate, MAP, pulse pressure, and the entire registered 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

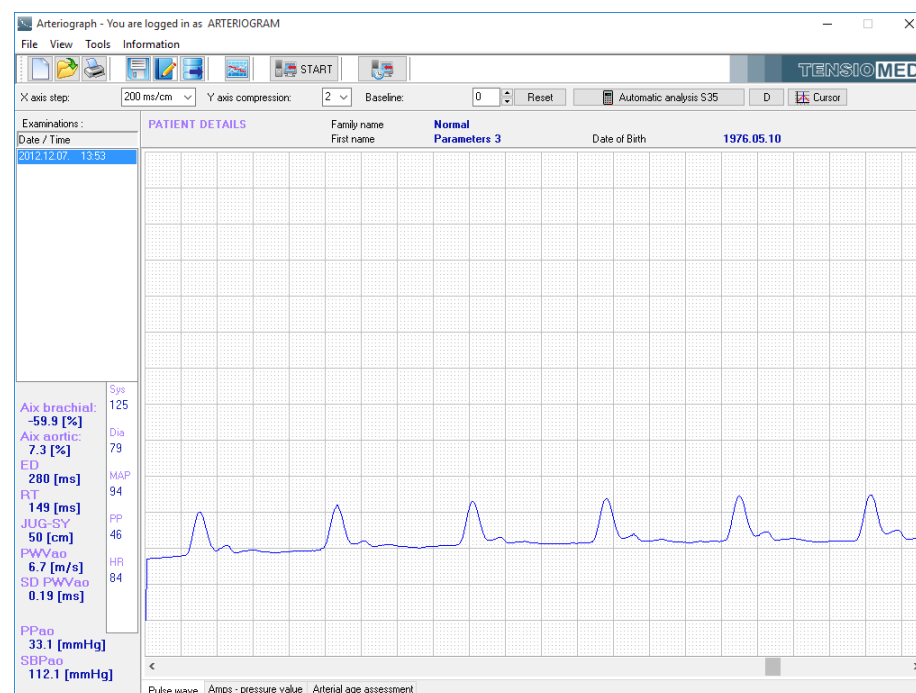
function only disrupts the data collection procedure of the software and does not affect the operation of the Device. To interrupt a measurement on the device the push button of the Arteriograph must also be pressed once.

If the Calculation of Ankle – Brachial Index was selected (See Section 5.4.1) a dialog window appears after the suprasystolic pulse wave recording phase is completed. Enter the formerly measured ankle systolic blood pressure here and press **OK**. The calculated value will appear under the blood pressure values in the Results field (see Section 3.2). 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 preceding the pulse wave recording. For measuring systolic blood pressure on the ankle, use of Doppler technique is suggested. However, if it is not available 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).



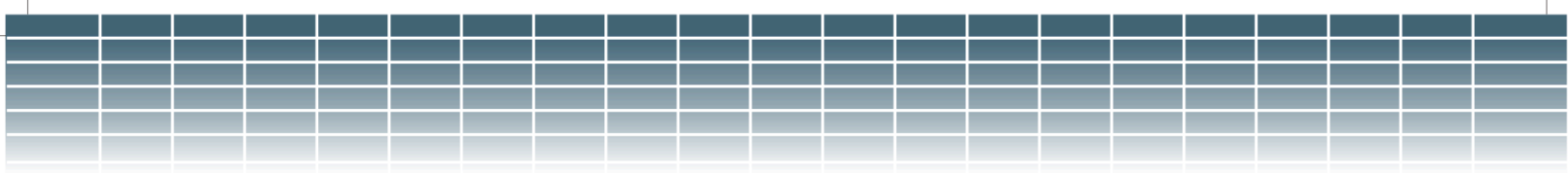
After the measurement is completed the automatically calculated blood pressure and arterial function data appear in the Results field (see Section 3.2), while the recorded pulse wave curves are displayed in the Data window (see Section 3.2).



Every examination is saved automatically. An already saved 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

Conditions (movement, arrhythmia, respiration, etc.) disturbing the measuring process may distort the shape of the recorded pulse wave, which may result in false hemodynamic parameter values. After the



measurement is completed its quality should be checked to decide whether the result of the subsequent analysis can be accepted.

We would like to note that the device and the software are sensitive to the appropriate input signal shapes. If the software detects biased signals containing artefacts, it does not provide arterial functional parameters. With this solution, 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 in 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

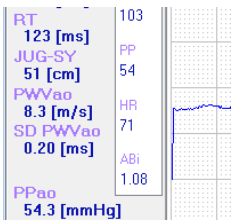
SD PWVao (see Section 5.1) is the standard deviation of the PWVao values calculated from the pulse waves that could be analysed by the algorithm of the software. This variable shows how much the PWVao data of each analysed pulse curve differ, therefore reflects on the identity of the recorded pulse wave 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.

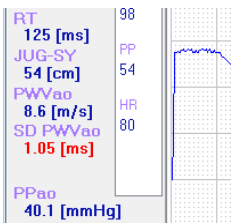
Borderline SD

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 5.4.5). If the manual evaluation would not provide better (<0.7 m/s) SD, the measurement should be repeated!



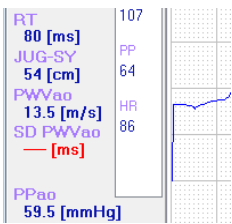
High SD

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 Results field to warn the User on the quality problem. Experienced users can use the manual evaluation to search for appropriate waves on the suprasystolic part of the measurement (see 5.4.5). If the manual evaluation would not provide better (<0.7 m/s) SD, the measurement should be repeated!



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 Results field to warn the User on the quality problem. The results of the analysis should be rejected, and the measurement should be repeated.



5.4.4.2 Quality control by visual inspection

Although the SD PWVao performs considerably well in detecting erroneous measurements, further visual inspection can help categorizing the type of the error. Consequently, it can be avoided when repeating the measurement. By visual inspection disturbances can also be detected in measurements that were categorized to be of good quality by the SD PWVao parameter.

There is no second systolic wave on the suprasystolically recorded pressure curves

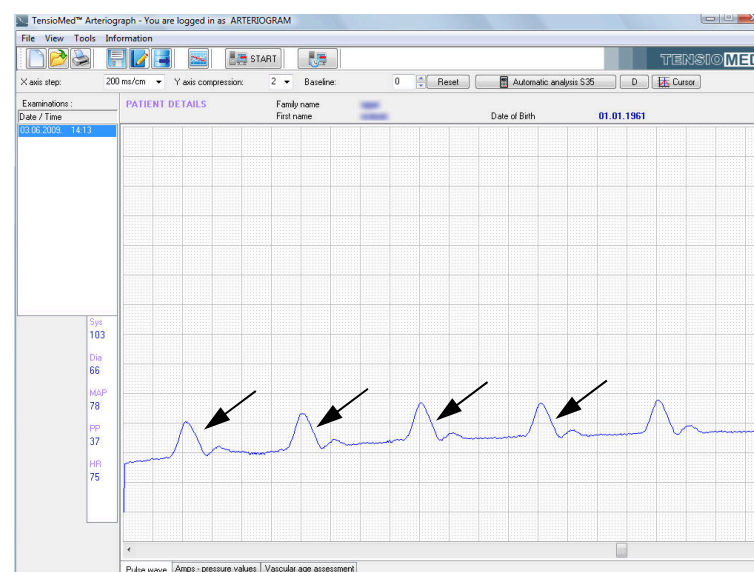
Arteriograph can only provide arterial function data when the first (direct) and second (reflected) systolic waves can be seen separately on the pressure curves recorded at suprasystolic cuff pressure. If these waves are not separated on the suprasystolic pulse curves, the common reason is that the cuff is too large or loosely fixed. In addition, rapid heart rate (> 90 / min), low amplitude reflected systolic wave (common at young age) can also cause the phenomenon. These can often be associated with the small, low amplitude of the suprasystolic curves, which may indicate dehydrated state, reduced circulating blood volume.

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

In this case no early and late systolic wave can be differentiated on the pulse wave form. Due to the larger cuff size or the looser fit, the cuff system loses its sensitivity to pick up higher frequency components of the oscillatory waves. This often leads to recording small amplitudes, which case is always indicated by the software with a warning message.

How to recognize: no reflected (second) systolic wave can be seen.

How to avoid: use a smaller cuff or tighten the cuff according to the instructions (see Section 5.3) or hydrate the patient properly.



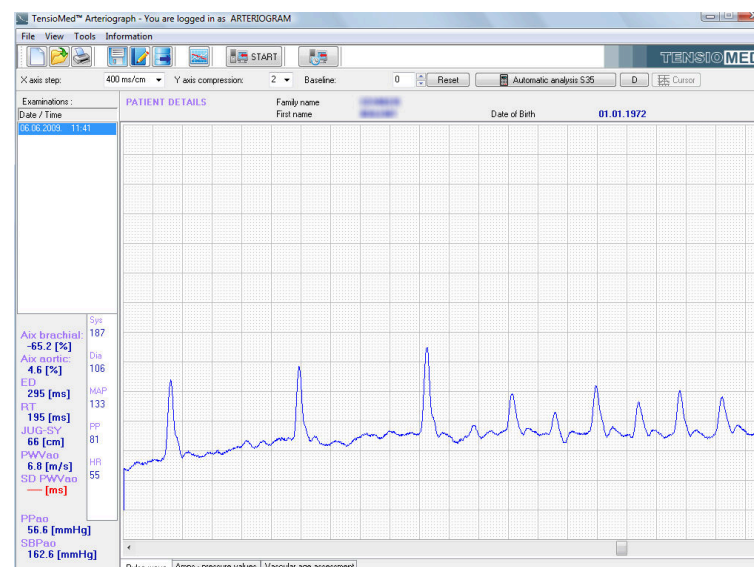
Arrhythmia

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. Manual evaluation (see Section 5.4.5) can help to find a regular sequence in the suprasystolic measurement phase.

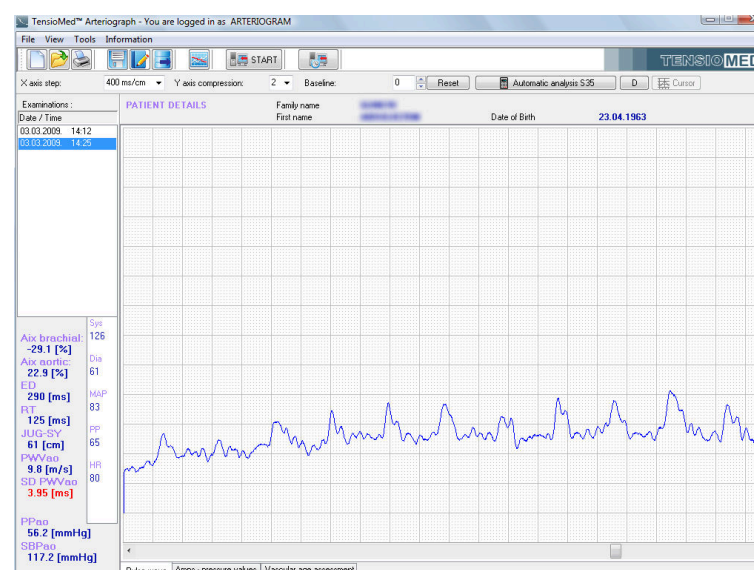
Tremor or mechanical vibration



Tremor introduces an unwanted high frequency noise into the measurement. This often leads to unrecognizable and not evaluable waveforms.

How to recognize: the measurement is noisy, a sawtooth-like signal is superimposed to 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).

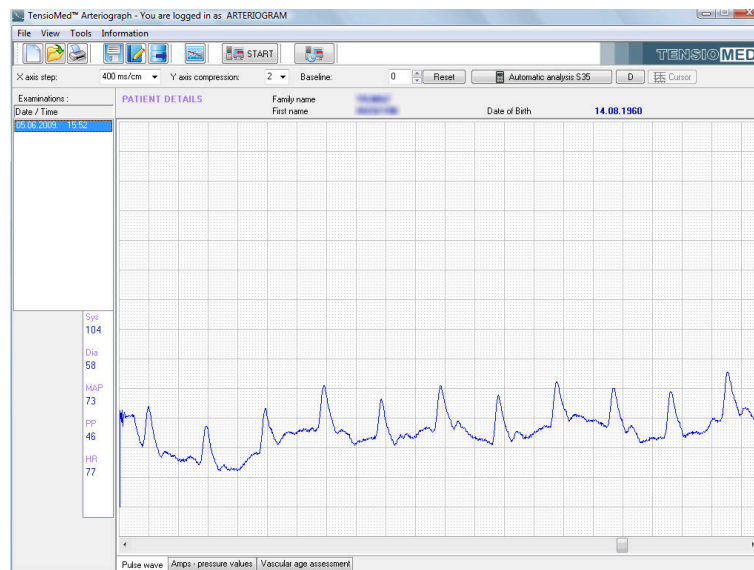


Movement artefacts

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

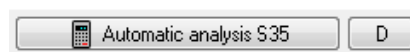
How to recognize: the baseline of the recording undulates or some pulse waves noticeably differ from the others.

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 an examination thereof you intend to analyse. You have two evaluation options available: automatic and manual.

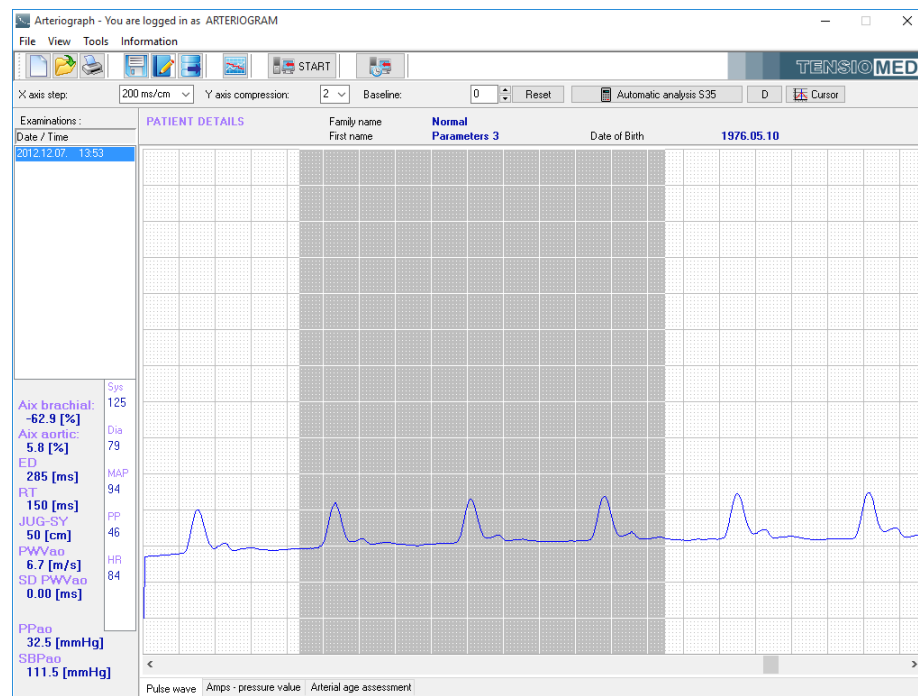


The former is fast and convenient. Automatic evaluation will take place immediately after a patient's examination is selected. The same can be achieved by clicking first on **Automatic analysis S35 (for suprasystolic data)** and then on button **D (for diastolic data)** after the results have been displayed. Most of the hemodynamic parameters described above (Section 5.1) will appear in the results window, under the list of examinations. During the automatic analysis the algorithm will analyse pulse waves of several heartbeats and calculate the mean of the results as well as the standard deviation of the PWVao (SD PWVao). However if there is only one evaluable pulse wave, no SD PWVao can be calculated.

For manual evaluation you have to go to the end of the whole measurement sequence by using the horizontal scroll bar at the bottom of the graphic area. (The pulse wave curves recorded at the suprasystolic pressure step are located at the end of the measurement sequence.) You can use the mouse for selecting arbitrarily any (or several) pulse wave recorded at the diastolic and suprasystolic pressure steps. Curves can be selected even from those recorded in the blood pressure measuring phase, but only that were recorded above the measured systole or in a ± 10 mmHg range of the measured diastole.

To select a series of pulse waves (or a single one) highlight (hold down the left mouse button while moving the mouse) those from the beginning to the end of the sequence. Only pulses (i.e. heart cycles) that are highlighted in their entirety are included in the analysis (see the picture below).

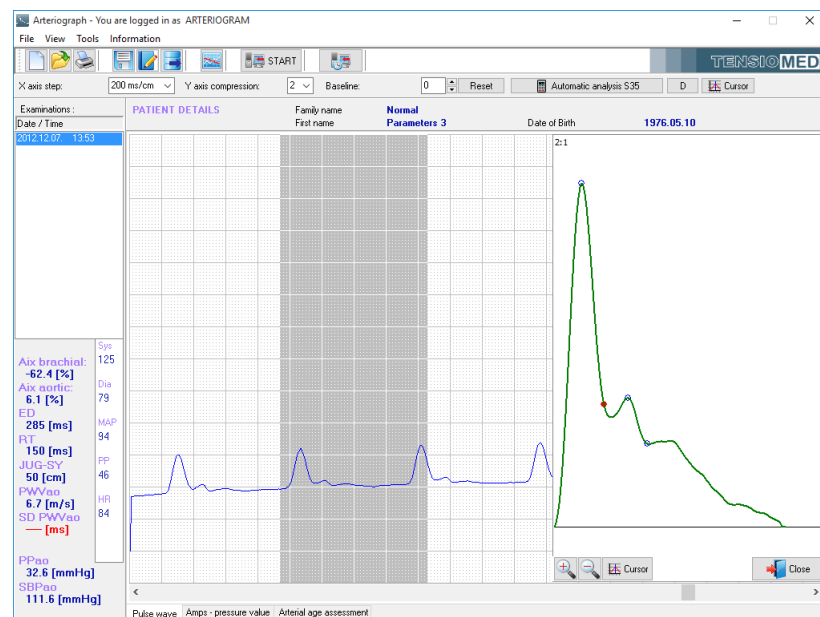
- When several pulse waves are selected for manual analysis the results are displayed in the same way as in a normal automatic analysis.



- In case a pulse wave of only a single heartbeat is highlighted – of either those that were registered at the suprasystolic or those registered at the diastolic pressure level – it will appear in a separate window displayed on the millimetre net. (Please note that in this case SD PWVao cannot be calculated.)

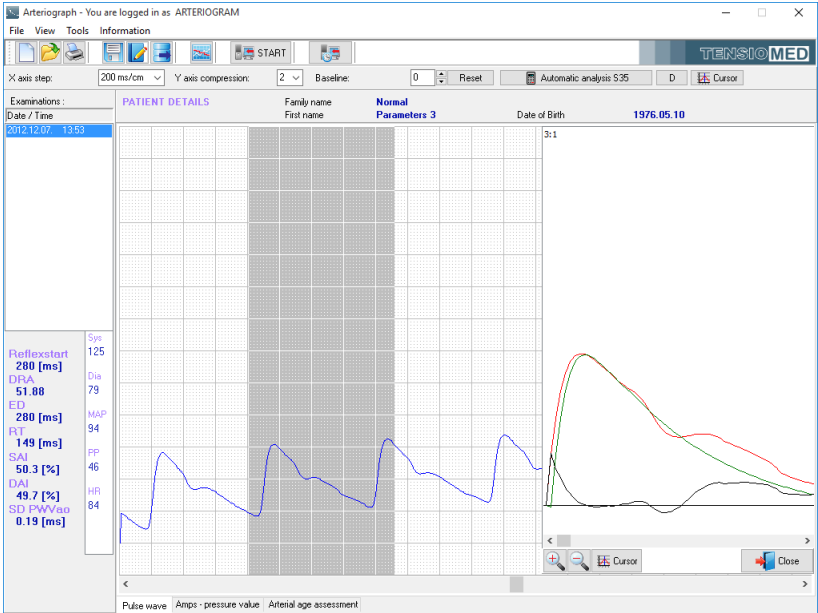
The said separate window can have two kinds of content:

- The one highlighted pulse wave at the suprasystolic pressure step is represented by a green curve. There are four markers shown on the curve, the meaning of those can be found below.

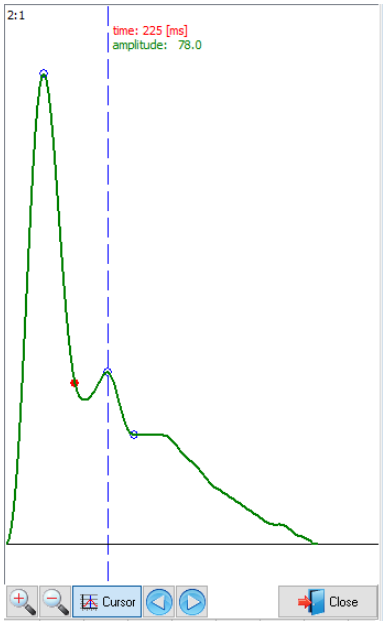


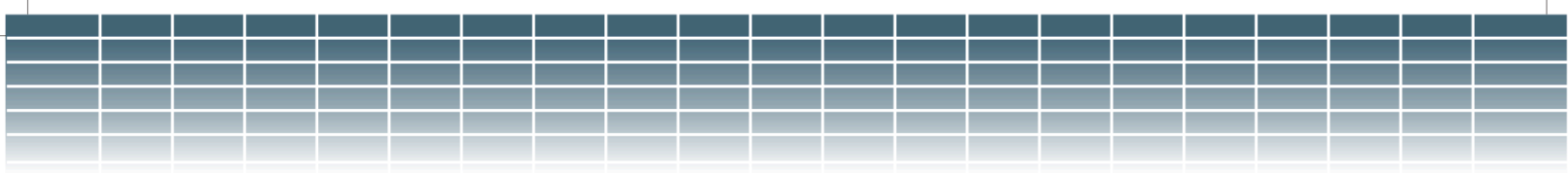
- When selecting only one pulse wave at the pressure step corresponding to the diastolic value several curves appear in the window: the original pulse wave

(represented by a red curve), the systolic component (green) and the diastolic wave component (black)

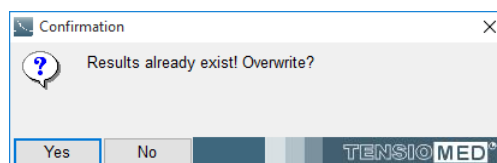


With use of the tools in the separate window the single pulse wave can further be examined. The curve can be enlarged and reduced in size within pre-set limits; see the relevant value of this in the upper left-hand corner of the window. Furthermore, you can examine the curves from point to point by means of a cursor that can be activated. The window can be closed separately. Characteristic points of the pulse wave curve are marked in this window. Blank blue circles represent the first and reflected wave peaks and the ejection duration (Dicrotic notch), respectively. Filled red dot represents the calculated return time. The return time is calculated as the time difference between specific characteristic points of the curve, therefore it does not necessarily fall to a characteristic point itself.





The 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.



This even allows saving results different from the ones calculated by the automatic evaluation. When an examination is opened it appears with the formerly saved arterial stiffness results. 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 5.4.7).

Note: Results of the evaluation are not saved automatically. For saving the results into the database 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:200 ms/cm

The scale of the horizontal, time axis of the pulse wave curve as displayed on the millimetre net can be set from 10 ms/cm to 1,600 ms/cm in the 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:2

Here the vertical, amplitude axis of the pulse wave curve, as displayed on the millimetre net, can be set. The set value indicates the vertical compression rate of the curve. In case the set value is 1, the curve will be displayed in full size. This function can be accessed directly from the toolbar (**Y axis step**) or by selecting a value under **Vertical axis compression** in the **View** menu.

Baseline shift

Baseline:0Reset

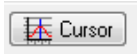
The pulse wave curve on the millimetre net can be moved upwards or downwards relative to the zero line. The original position can be restored by clicking on the **Reset** button.

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 millimetre net.

Cursor



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

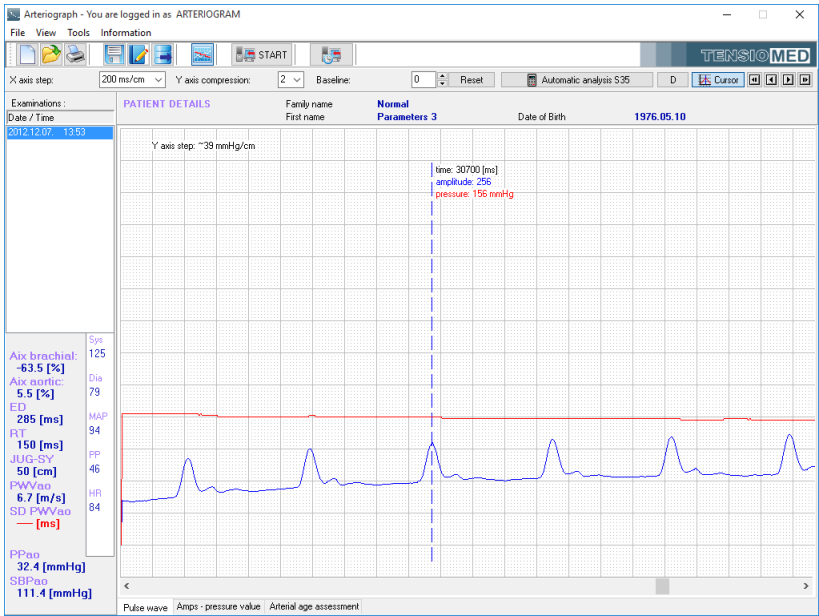


When the button is on the control tools appear. With use of these the cursor can be moved in small or big steps.

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

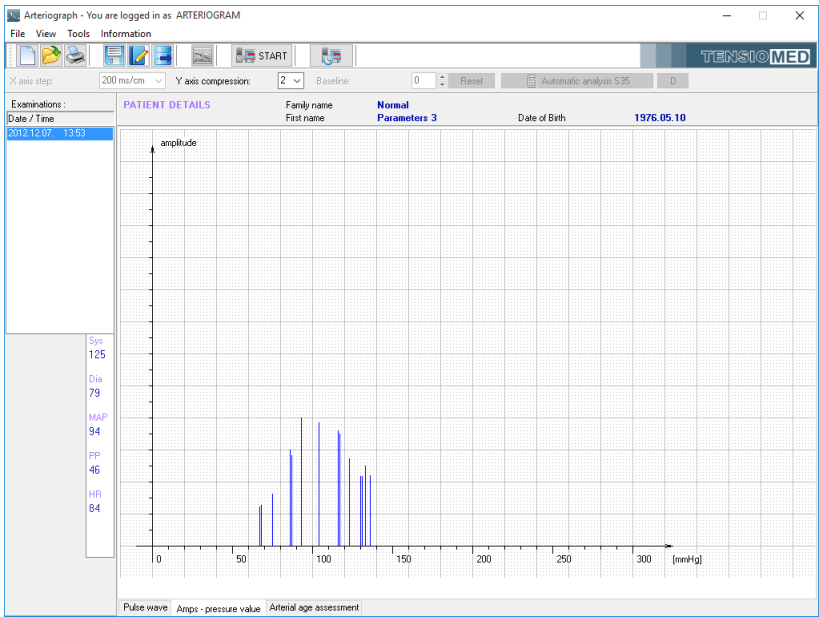
Note: The oscillatory signals are not calibrated and therefore should not be considered to represent true pressure values.

The above mentioned functions are illustrated in the picture below.



5.4.5.2 Oscillation amplitudes during blood pressure measurement

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



5.4.5.3 Vascular age assessment

By clicking on the **Vascular age assessment** tab of the measurement window the estimated vascular age of the measured patient can be displayed. The same function can be accessed by selecting the **Vascular age assessment** command under **View menu**.

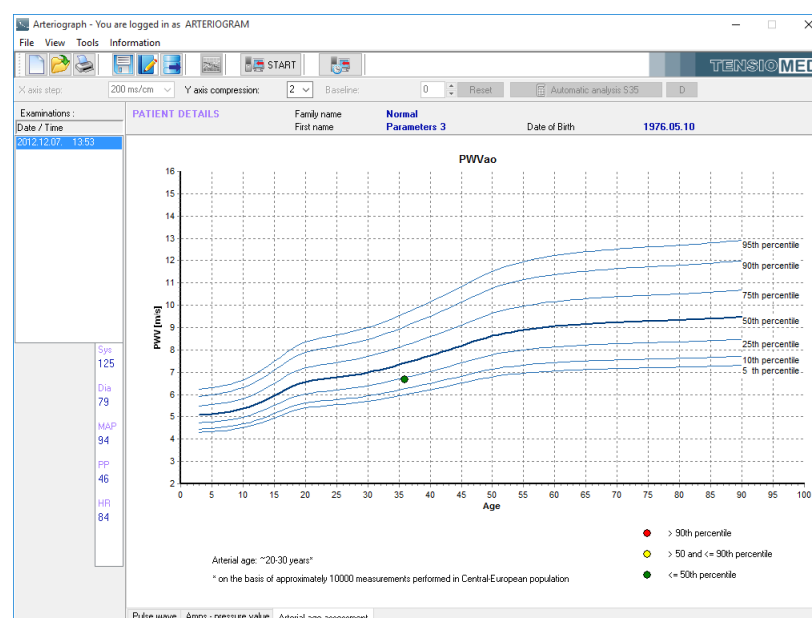
This tab shows the Age – PWVao relationship with smoothed reference percentile curves.

Note: Percentile is a value below which a certain percentage of the known measurements fall; e.g. the 75th percentile is the value below which 75% of the observations can be found. Age-specific percentile curves show certain percentiles in different ages.

Note: The reference curves were derived from a healthy central - European population including approx. 10 000 subjects.

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

- 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.




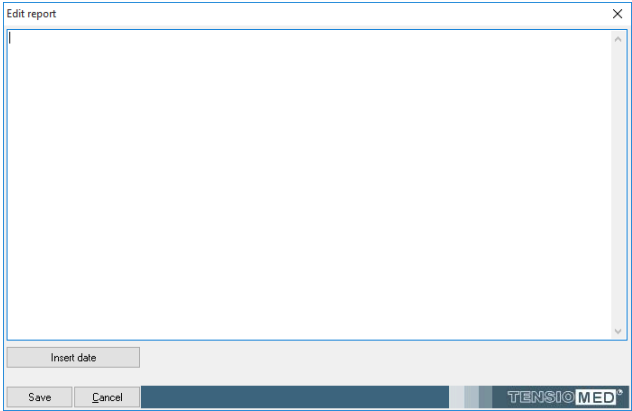
5.4.6 The measurement Report

The Report is a printed summary of the measurement results. It includes patient details, all the calculated hemodynamic parameters, characteristic 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 edit 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 suggestion, which can be saved by clicking on **Save**. The current date can be inserted 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 **Options** under **Tools**. In the dialog box choose the **Printed Report** tab where you can specify the following:

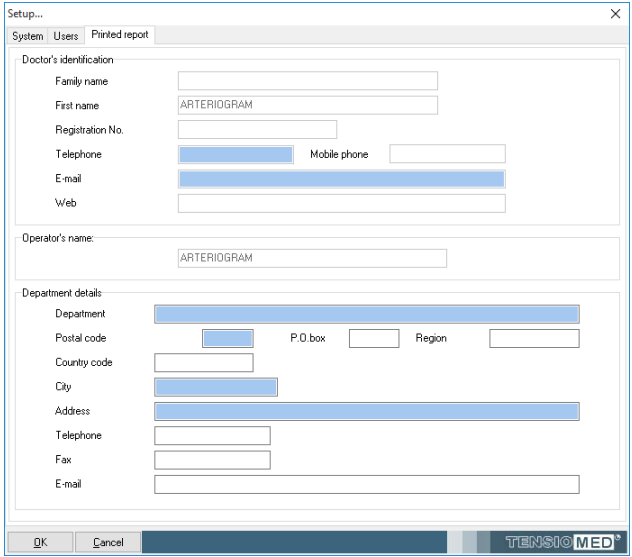
- Doctor’s identification data
- Department details
- Operator’s name

Department details along with the doctor’s name and registration number will appear 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 will appear in the Study data section of the printed report. It is measurement

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.

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.

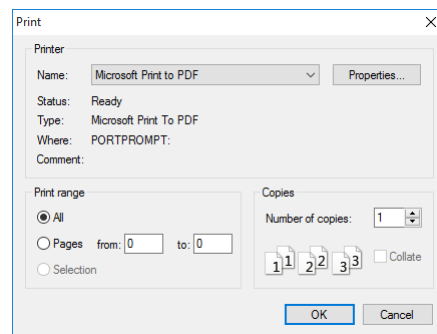


5.4.6.2 Print the Report

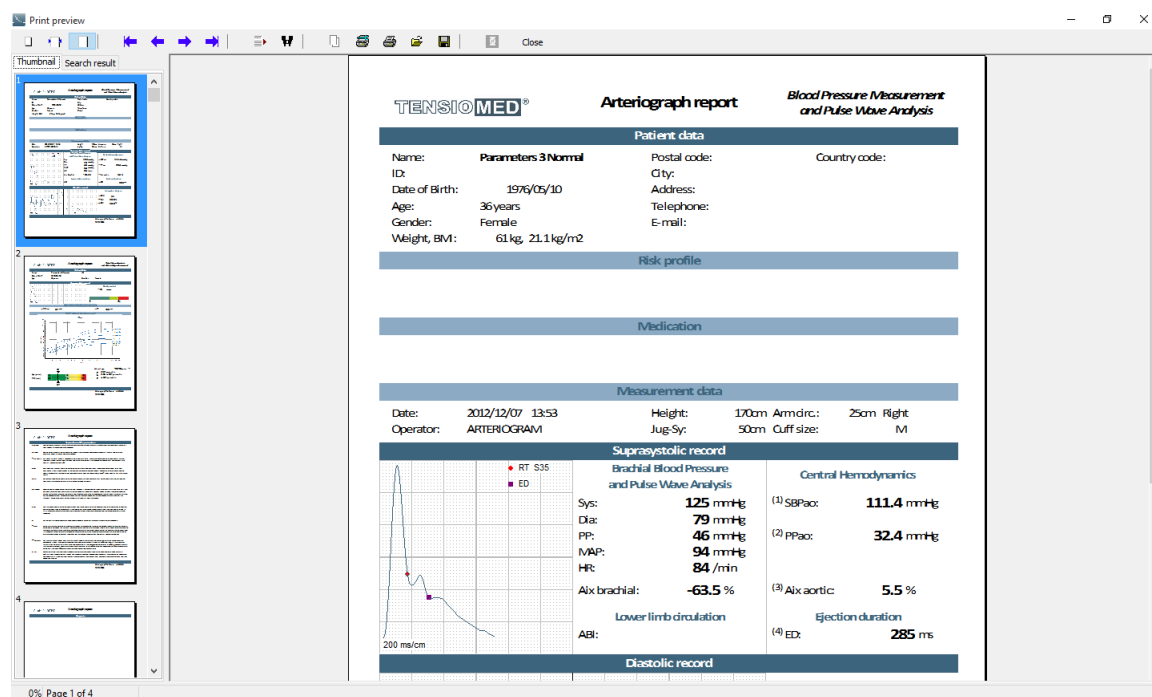


You can print out a Report by choosing **Print preview and print** under the **File** menu or clicking the **Print preview and print** button on the toolbar.

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 to continue.



The print preview screen appears:



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

Zoom tool



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

Navigation tool



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

[illegible]

The Report printed out by the Arteriograph Software will contain the following:

TENSIO MED® **Arteriograph report** *Blood Pressure Measurement and Pulse Wave Analysis*

Patient data		
Name: Test Elisabeth	Postal code:	Country code:
ID:	City:	
Date of Birth: 03/08/1950	Address:	
Age: 56 years	Telephone:	
Gender: Female	E-mail:	
Weight, BMI: 51 kg, 18.7 kg/m ²		

Risk profile

Medication

Measurement data

Date: 26/03/2007 07:43 Height: 165cm Arm circ.: 51cm
Operator: Jug-Sy: 51cm Cuff size:

Suprasystolic record

Brachial Blood Pressure and Pulse Wave Analysis

Sys: 139 mmHg SBPao: 139.3 mmHg
Dia: 85 mmHg
PP: 54 mmHg PPao: 54.3 mmHg
MAP: 103 mmHg
HR: 71 /min
Alx brachial: -7.7 % Alx aortic: 33.7 %
ABI: Lower limb circulation ED: 340 ms

Diastolic record

Volumetric Analysis

DRA: 51
SAI: 74.4 %
DAI: 25.6 %

TensioMed™ Software v.3.0.0.0
04/TL0062 00913

TENSIO MED® **Arteriograph report** *Pulse Wave Analysis and Arterial Age Assessment*

Patient data	
Name: Test Elisabeth	ID:
Date of Birth: 03/08/1950	Gender: Female
Age: 56 years	

Suprasystolic record

Quality control
SD: 0.20 m/s

Pulse Wave Velocity measurement
PWV: 8.3 m/s RT: 123 ms

PWV - Arterial Age Assessment

PWVao

Age (years)

PWV (m/s)

Arterial age: ~40-50 years*

* on the basis of approximately 10000 measurements performed in Central-European population

TensioMed™ Software v.3.0.0.0
04/TL0062 00913

Page 1:

- **Patient details.** The data specified when entering the patient's data are shown here including a user-defined parameter and its value provided it is set (Section 5.4.1). The space for missing or undefined data will remain blank.
- **Risk profile.** The previously entered risk profile (see Section 5.4.2.2) appears here.
- **Medication.** The list of medications entered previously (see Section 5.4.2.2) appears 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 represented here, if this option was selected (see Section 5.4.1). A characteristic pulse wave is shown with the points of the Return Time (**RTS35**) and Dicrotic notch (Ejection Duration; **ED**) indicated on it. The return time does not necessarily fall to a characteristic point on the curve (see Section 5.4.5).
- **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 a section 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 defined 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 SW** on the right-hand side.

Page 2:

- **Suprasystolic record.** The first part of this page contains the quality control of the measurement. A section of pulse wave curves recorded on the suprasystolic pressure step are shown in a graph to enable visual control over the quality of the waveforms. The value of SD PWVao is also represented here.
- **Pulse Wave Velocity measurement.** This part highlights 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 graph legend. The estimated arterial age of the patient is also given here in decades except for pooling over the vascular age of 60. A more precise estimation of the patient's arterial age can be seen on the SD PWVao parameter graph, which is a simplified visualization of the reference percentile values for the patient's age. It shows the patient's position relative to the reference population. The measured value is indicated in the graph, also showing the estimated arterial age at the top.

Page 3 (optional):

- **Medical Report.** Printed only if the **Edit report** function was used (see Section 5.4.6.1). This page includes only the patient details and the edited medical report.

Note: The Report is always printed out in A4 size. It will contain only as much information as was entered previously or was calculated in the course of the analyses, which also means that a Report can be printed out with only the patient's data appearing.

Note: Cut-off (critical) values for the different parameters can be found in the available scientific literature addressing vascular age and arterial function.

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 destination 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*).

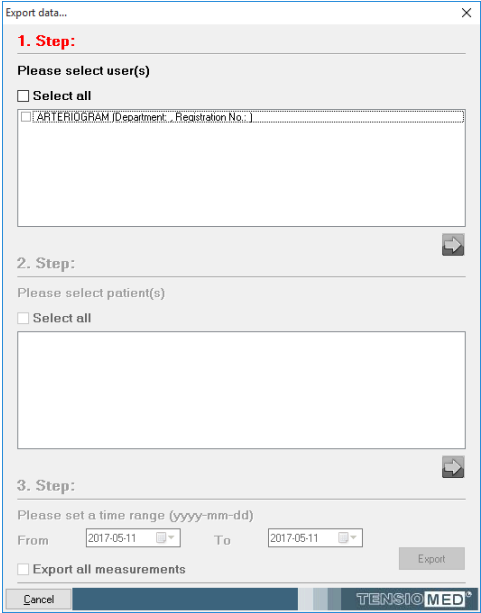
As a next step the default e-mail client – if there is any – is loaded automatically with the generated .pdf file attached to a new letter.

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.

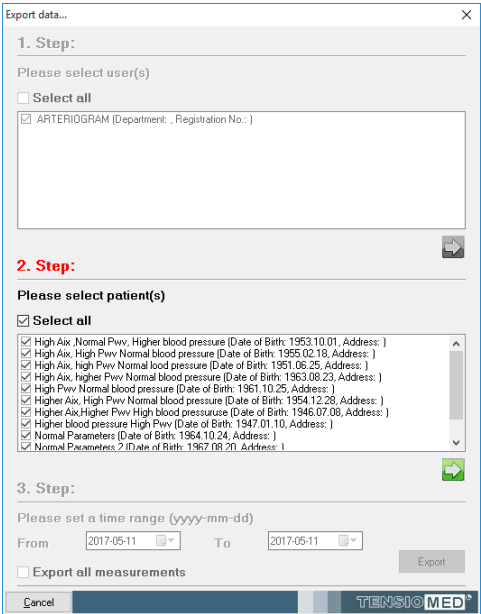
Step 1 Select a User whose patients’ measurement you would like to export by clicking the checkbox next to it. The **Select all** option is a quick way to select all the listed users. All the registered users are listed in this window. Selection is confirmed by clicking on the arrow.



Step 2 Select the patients whose measurements you would like to export by clicking on its row. All the patients belonging to the selected user are listed here in alphabetical order of the family name.

In case 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 family name of the given patient. The built-in search is not case sensitive.

Multiply selection can be done in the common Windows way (using Ctrl or Shift while clicking). The **Select all** option is a quick way to select all the listed subjects. Selection is confirmed by clicking on the arrow.



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

Export data...

1. Step:

Please select user(s)

☐ Select all

☒ ARTERIOGRAM (Department: , Registration No.:)

2. Step:

Please select patient(s)

☒ Select all

☒ High Aix, Normal Pwv, Higher blood pressure (Date of Birth: 1953.10.01, Address:)

☒ High Aix, High Pwv Normal blood pressure (Date of Birth: 1955.02.18, Address:)

☒ High Aix, high Pwv Normal blood pressure (Date of Birth: 1951.06.25, Address:)

☒ High Aix, higher Pwv Normal blood pressure (Date of Birth: 1963.08.23, Address:)

☒ High Pwv Normal blood pressure (Date of Birth: 1961.10.25, Address:)

☒ Higher Aix, H

☒ Higher Aix, H

☒ Higher blood

☒ Normal Pwv

☒ Normal Pwv

2017. május

H K Size Cs P Szó V

24 25 26 27 28 29 30

1 2 3 4 5 6 7

8 9 10 11 12 13 14

15 16 17 18 19 20 21

22 23 24 25 26 27 28

29 30 31 1 2 3 4

3. Step:

Please set

From 2017-05-11 To 2017-05-11

☐ Export all measurements

Export

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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.

Export data...

Export patients data...

Export measurements...

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Step 5 When the export is completed a message window will pop up confirming on the successful save.

Information

File saved successfully!

OK

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The save destination of the completed text file can be selected. 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 statistical packages (e.g. SPSS, SAS).

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

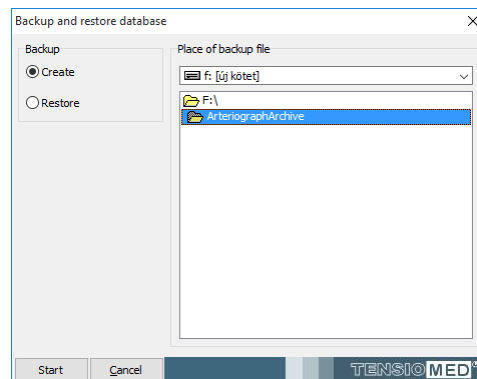
5.4.8 Backup and restore the database

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

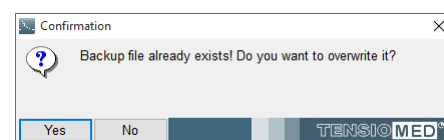
The Backup and restore dialog window appears, where you can set whether to make or to restore a database. The destination directory can also be selected.

5.4.8.1 Backup data

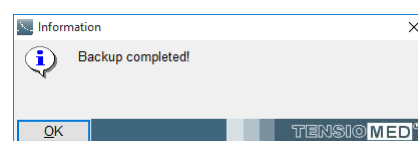
In the Backup field select **Create** to start the backup process. Also select the destination directory for the backup file.



In case 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**.

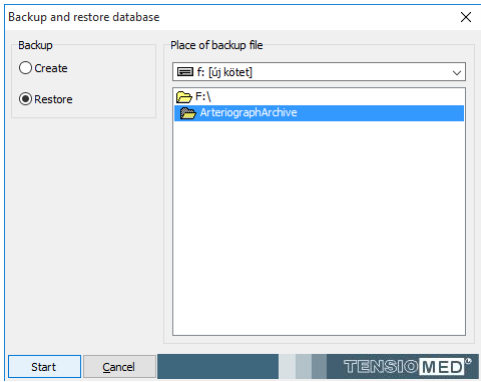


An information window appears if the backup is successfully completed.

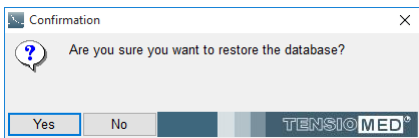


5.4.8.2 Restore data

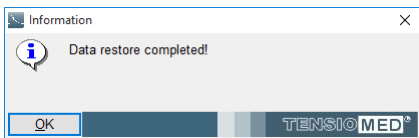
In the Backup field select **Restore** to start the restoration process. Also select the destination directory for the backup file.



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



An information window appears when the restoration is successfully completed.



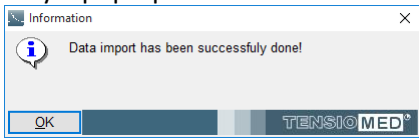
5.4.8.3 Import previous database

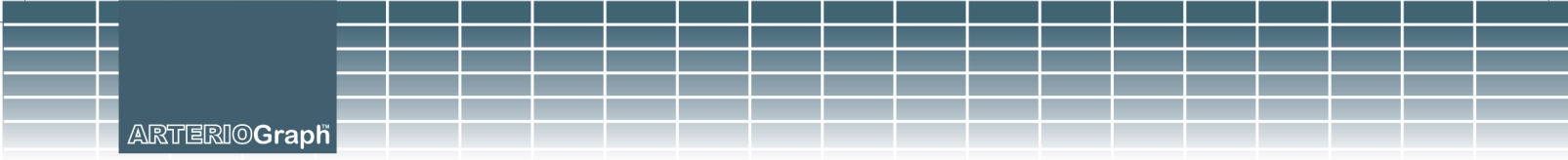
If you have a previous version of Arteriograph database on your computer the **Convert previous database and import data** command under **Tools** menu helps to convert the measurements into the new database format. Select the patient list (.pat) file in the Regisztratumok folder under the previous installation 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.

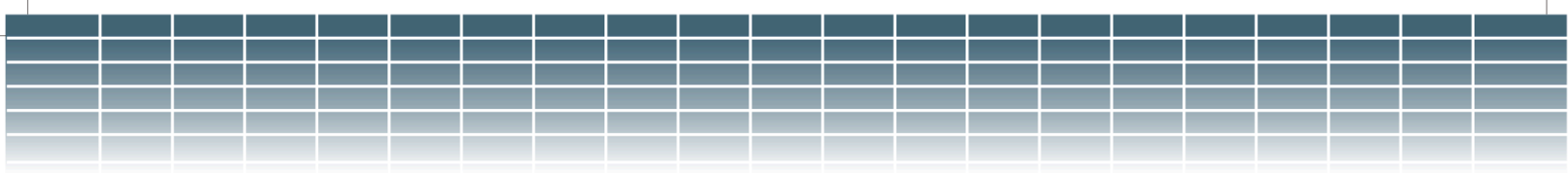
Successful conversion is confirmed by a pop-up window.





6. Troubleshooting

Problem	Possible causes	What to do
No communication	The device is not recognized by the PC	Go to Control Panel/Bluetooth Devices and check whether the device is present. 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 in arrhythmic patients.
	Tremor	If possible, try to terminate tremor.
No print preview	No printer have 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 opened or the database was damaged.	Import the database by following the instructions of Section 5.4.8.3.
Cannot send e-mail successfully	No e-mail client is installed to the PC.	Install an e-mail client and set it to be the default one.



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. In case the Device cannot measure blood pressure (e.g. due to motion), measuring will be disrupted.

Example:

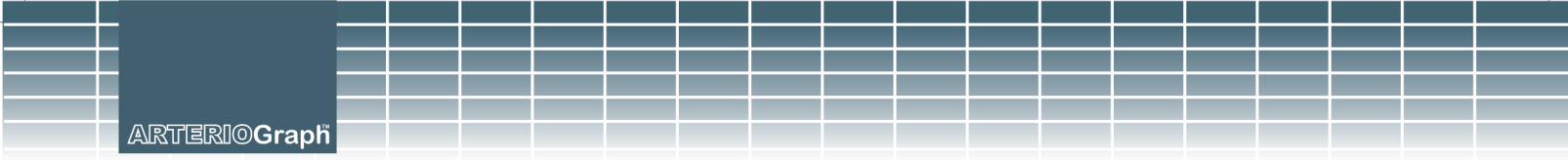
Err 32

The codes of the error flags 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"	Measuring 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 choking 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 put on the patient.
35	"measuring disrupted"	For some reason (e.g. the user presses the button) measuring is disrupted.
37	"the cuff pressure is exceeded 300mmHg"	During the blood pressure measurement the cuff pressure has reached or exceeded the maximum allowable pressure of 300mmHg 's value.
90-99	"Device error"	Blood pressure measuring failed for some Device error or the battery is low.
100	"Faulty measuring result"	The calculated results cannot be considered as a real blood pressure value or the patient is having arrhythmia.
101	"motion"	The measuring conditions, e.g. the patient's movement, interfere with the process of measuring.
102	"no pulse detected"	For some reason the Device does not detect the cardiac pulses.
110	"Faulty measuring result"	The signals are insufficient for blood pressure calculation. (Artefacts, arrhythmia.)
111 112 113	"Faulty measuring result"	The calculated results cannot be considered as a real blood pressure value. (The most likely reason is noisy measurement signals.)
115	"Faulty measuring result"	The pulse rate cannot be calculated or cannot be considered as a real value.



53




7. Technical Specification

Power supply:	Four AA long-life alkaline batteries or rechargeable 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 XP with Service Pack 2 or newer 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: 2 years)
Measuring 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/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: 300mmHg ; Maximum measurement time: 180 seconds
Deflation:	Automatic, stepwise

7.1 Electromagnetic compatibility

Electromagnetic emissions		
The (version: TL2) device is intended for use in the electromagnetic environment specified below. The customer or the user of the (version: TL2) device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The (version: TL2) 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. The (version: TL2) 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity			
The (version: TL2) device is intended for use in the electromagnetic environment specified below The customer or the user of the (version: TL2) 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0,5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 s	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the (version: TL2) 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.			

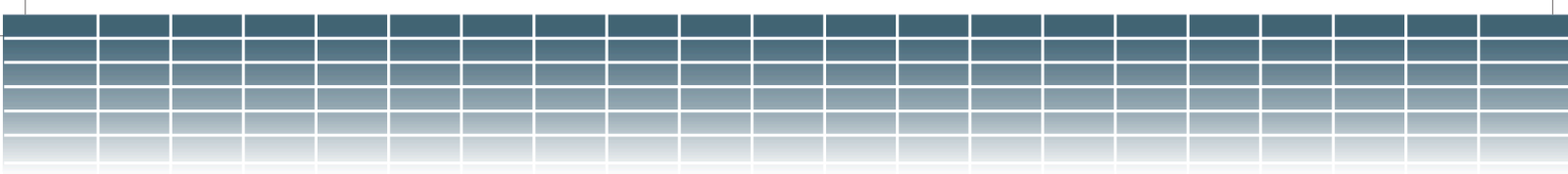
Electromagnetic immunity			
The (version: TL2) device is intended for use in the electromagnetic environment specified below. The customer or the user of the (version: TL2) device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 V _{eff} 150 kHz – 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the (version: TL2) device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1,2√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5 GHz	3 V/m	d=1,2√P 80 MHz – 800 MHz d=2,3√P 800 MHz – 2,5 GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer 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 strengths 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 (version: TL2) device is used exceeds the applicable RF compliance level above, the (version: TL2) 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 (version: TL2) 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 (version: TL2) device			
The (version: TL2) device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the (version: TL2) device can help prevent <i>electromagnetic</i> interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the (version: TL2) device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz – 80 MHz d=[3,5/3]√P	80 MHz – 800 MHz d=[3,5/3]√P	800 MHz – 2,5 GHz d=[7/3]√P
	0,01	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> 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. 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 20 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 and exerts pressure on it when the device is in use.
Intended user profile	Doctor, medical staff.
Use environment	Medical outpatient, medical diagnosis where applicable. See sections 1.1. and 1.5. for details.
Operating principle	Oscillometric method

My notes



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