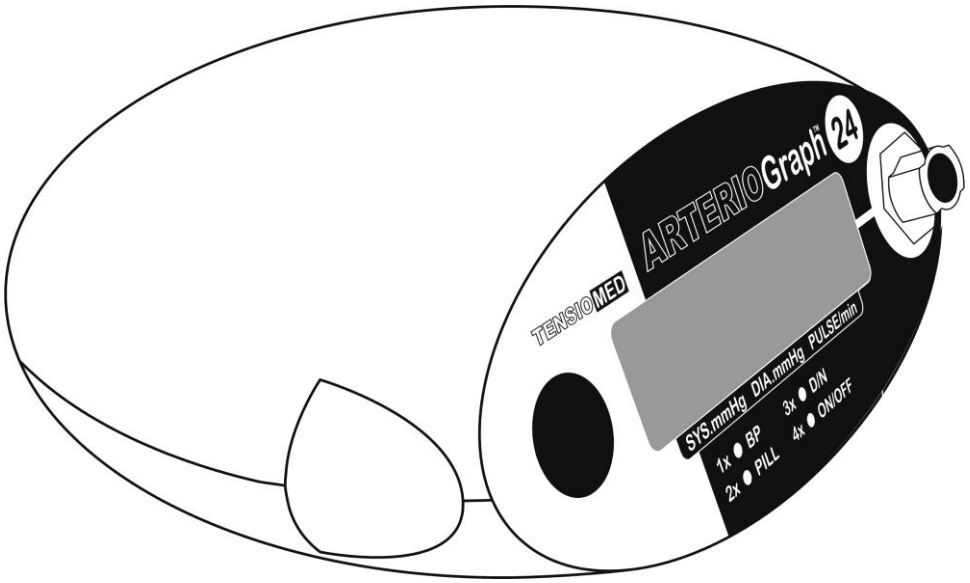
TENSIOMED
THE ARTERIOGRAPH COMPANY

ARTERIOGraph™ 24

Device for the 24hour measurement
of arterial function (stiffness) and peripheral blood pressure

Instruction for use

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



With wireless communication

Bluetooth

CE 0197

TensioMed® Arteriograph24-03v10-00
Revised: 05-04-2024

Table of contents

1. Introduction and the intended use of the device

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

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

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

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

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

If the patient has a pacemaker, this does not affect the applicability of the Arteriograph24.

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 Arteriograph24. Do not use the device on patients if high frequency electrosurgical equipment is applied on them.

For a patient being in a hyperbaric oxygen chamber, the Arteriograph24 should not be used.

In case of a skin disease or wound on the upper arm where the cuff is planned to be placed, the Arteriograph24 measurement should not be performed.

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

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

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.

The device measures the brachial blood pressure with an oscillometric method. Then the device inflates the cuff to the suprasystolic blood pressure and then deflates the cuff. The whole process lasts for approximately 2 minutes.

Arteriograph24™ device is controlled by the TensioWin software. The measurement protocol and the blood pressure readings are transferred via Bluetooth communication from and to the physician's PC, respectively.

Automatic measurements can be set for up to 72 hours of length, with frequencies ranging from 10 to 90 minutes. Separate measurement frequencies can be set for the “active” daytime, “passive” night-time, and for a third “special” period.

The measured data are stored in the memory of the device.

Apart from the programmed measurements, the patient may start a manual measurement. This can be done by simply pushing the button on the device once. All manually initiated measurements are stored and displayed on the software report. The storage capacity of the device is 1000 measurements.

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

TensioMed is not responsible for printing or clerical errors.

1.1. Contents of the manual

This manual helps you in setting up and starting to use the Arteriograph24™ device.

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

1.2. Supplementary information and helpful hints

Cleaning/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 the connected rubber tube.

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 certain disinfectants. If you have such a patient or are unsure, remove possible residues with careful washing. The cuff sleeve can be washed in a washing machine at max. 30 °C using a mild washing liquid (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 the cuff in place over 24 hours.

The Velcro must always be fastened before washing.

The handling, storage, wrapping, substance-conservation and transportation of the producer's devices are defined in accordance with the general quality control requirements.

The device meets the requirements of the following standard:

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

1.3. Warranty

TensioMed Ltd. offers a **2-year warranty** for a brand-new device. Any repair and device calibration within or beyond the warranty period are performed by TensioMed Ltd. in the service station of the company (Cziráki Street 26-32, Building A, 44/b, Budapest H-1163, Hungary). The **service life** of the device is **8 years,** and its **shelf life** is **10 years.**

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

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

Central office and service:

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

1.4. General Information, warnings and precautions

We suggest carefully studying the instruction for use of this device and to note the listed precautions.

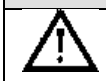
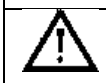
The user of the Arteriograph24™ instrument should be able to read, understand and learn the contents of the user manual. When using the TensioWin software, it is a physical requirement to see and understand the messages and inscriptions of the software. It is also a minimum requirement for the user to be able to fit the cuff, to measure the distance between the sternal notch and the pubic bone or the height of the patient and to measure the arm circumference. Furthermore, they shall be capable of operating the software on the computer. Performing the measurement does not require a medical doctor, however only a medical doctor is allowed to evaluate the result.

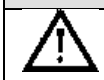
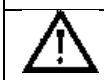
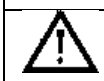
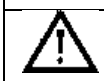
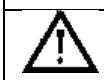
We have good practical experience with the use of Arteriograph24™ in the age group above 3 years, which is the intended use of the instrument.

There is no direct restriction regarding the weight of the patients, because if the cuff can properly be placed onto the upper arm, and the device is able to collect signals with adequate quality for the evaluation, the examination can be performed on overweight or obese patients. However, in these cases some of the performed measurements might be automatically excluded from evaluation by the software. Therefore, the use of Arteriograph24™ may be limited in the case of extremely overweight patients.

There is no special height limit when using the instrument. On the other hand, for extremely short or tall people, measuring the JUG-SY distance should be preferred over measuring their height.

The Arteriograph24™ shall be used with 1.5 V alkaline batteries, size AA.

Attention!	
	If the device is not used for a longer period (more than 2 hours), remove the batteries from the battery compartment. Furthermore, please, keep the device out of reach of children if it is out of use.
	Pay special attention when utilising ambulatory blood pressure measuring devices to patients with serious mobility or other impairments, unconscious or otherwise incapable patients and patients with coagulation disturbances. For children it is also recommended to use the unit with special care. Children should not use the device on their own!
	The device cannot be used on those patients, who do not remain calm during the measurements for any reason (e.g. Parkinson disease or other diseases with tremor). It is not an exclusion criterion, but regarding the quality of the recordings it is unfavourable if the patient is not in a proper condition psychologically/mentally.
	Devices, which are withdrawn from the use, should be collected selectively in order to provide an effective recycling, reducing the unfavourable effects on the environment and human health.
	Only use with cuffs supplied by TensioMed Ltd! Use of cuffs supplied by a third party will 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 transferring the data to the PC.
	Do not use the device when it is exposed to mechanical vibration (e.g. in vehicles).
	Do not expose the device and its parts to strong sunshine.
	Extreme temperatures, humidity, and altitude can affect instrument performance.
	The device cannot be repaired during use. Disassembly or modification of the device is **not** permitted! Please refer to section 1.3. The manufacturer does not accept any liability for damage or malfunction in the event of non-compliance.
	Avoid fluid contact and/or strong physical effect on the device.
	The pressurized cuff can cause loss of signals of other medical devices used on the same arm.
	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 may occur.

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 pneumatic connector of the cuff from the device and remove the cuff from the arm.
	Too frequent or too long measuring periods might cause blood flow disturbances in the arm. Ensure by the proper programming of the device that there is enough time for blood flow recovery.
	Avoid the kinking of the hose during measurement.
	Do not use the device on an arm, which is being injected with intravenous injection.
	Do not use the device on patients suffering from blood coagulation disturbances.
	If the patient had surgical operation on any artery/vein of his/her arm (e.g. arterio-venous shunt) or permanent/temporary intra-arterial catheter has been installed, do not use this arm for the measurement.
	If the patient had a radical mastectomy, the cuff should not be installed on the same side, where the operation was performed.
	In case of any skin disease, any inflammation or any wound on the arm, the cuff should be installed onto the intact arm. If both arms are involved, the physician must decide, assessing whether the benefit gained by the examination is superior compared to the risk of the measurements.
	The Arteriograph24™ device can be used on pregnant women as well.
	Do not use the device on neonates or infants! Cannot be used on persons below 3 years of age!

2. The Arteriograph24 device

2.1. Explanation of symbols

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

1. Function button (Offering four menu options),
2. Command symbols,
3. LCD,
4. Air connector.

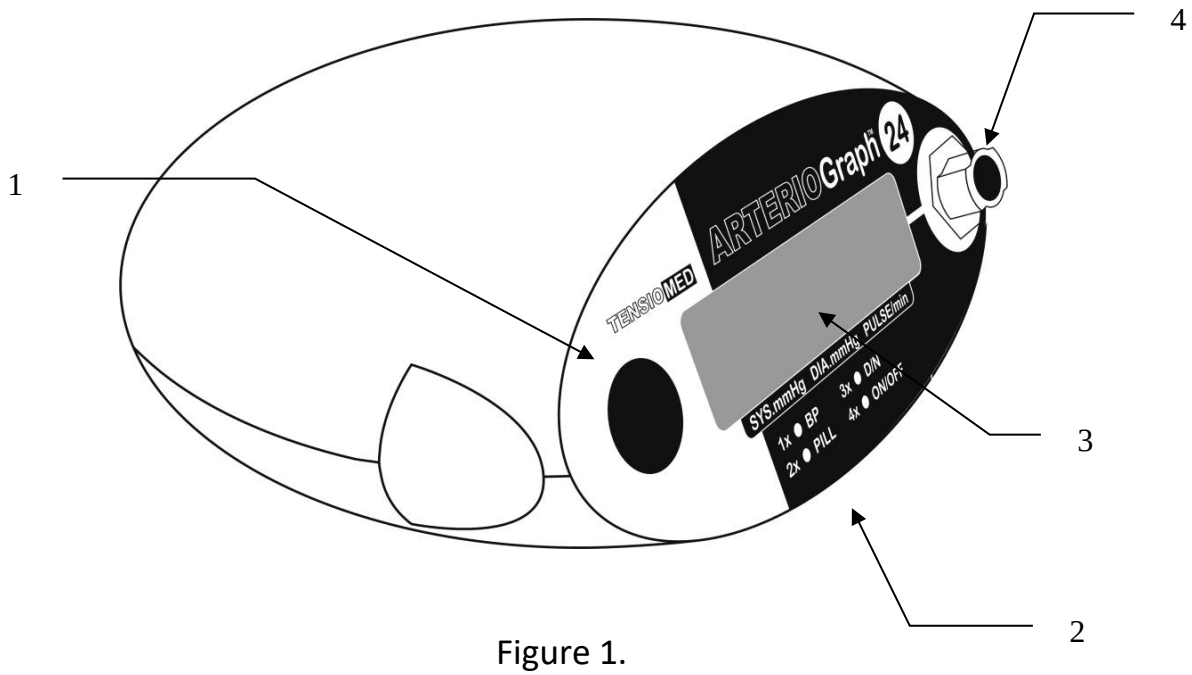
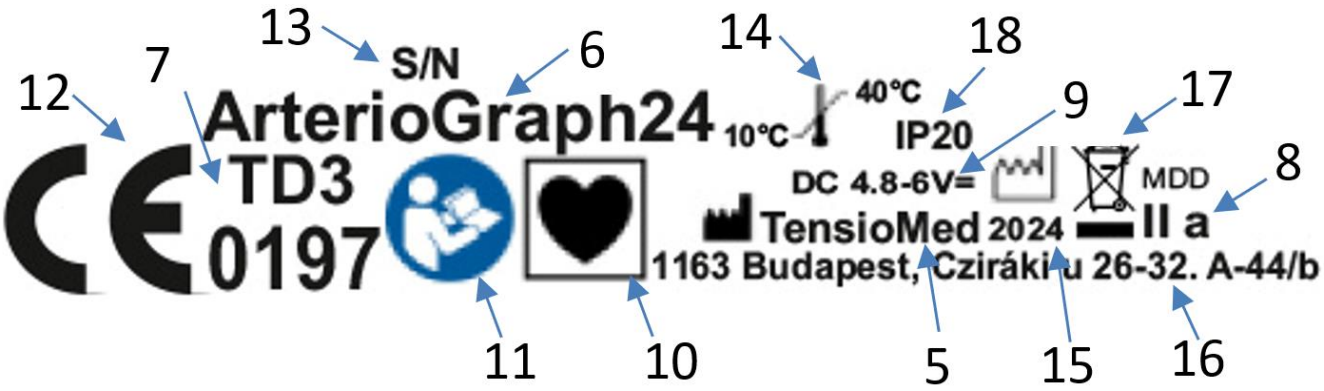


Figure 1.

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

5. Name of the Manufacturer
6. The name of the device
7. The type (version) ID of the device
8. The classification of the MDD requirements: IIa
9. The nominal voltage range applicable with batteries
10. The classification of the protection against electric shock
    Classification: patient's side: CF.
11. Calling attention to reading this instruction for use thoroughly
12. Certification mark guaranteeing that the apparatus complies with the prescriptions and requirements of the European Union.
13. Serial number
14. Operating ambient temperature range
15. Year of the manufacturing
16. Address of the Manufacturer (TensioMed)

17. The discarded devices must be collected in order to get more efficient reuse and recycling, as well as harmful effects on human health and for the environment of the ingredients are selectively collected.
18. Level of protection against any liquid or grainy material filtering into the device (IP N_1N_2)
    N_1=2: Protected against solid foreign objects of 12,5mm and greater
    N_2=0: Not protected against water



2.2. Accessories

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

- Three cuffs of different sizes (see below)
- TensioWin software installation CD and flash drive with the instruction for use
- Instruction for use

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

The cuff sizes are as follows:

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

The manufacturer of the cuffs:

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

2.3. Preparing the device for operation

Arteriograph24 is a battery-operated device.

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

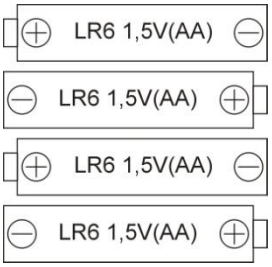


Figure 3.

The clock circuits of the device are powered by a CR2032 battery, therefore the clock time is stored and resetting the time is unnecessary between battery changes. Each time a measurement protocol is transferred to the device from the PC, the clock on the device will update.

If you do not intend to use the device for a long period of time (more than 2 hours), remove the batteries and store them in a cool and dry place. Do not apply heat to the batteries, or an internal short circuit may occur.

Dispose of the spent batteries immediately in an environment-friendly way.

Your computer must have active Bluetooth connection capability. The Bluetooth icon appears in the system tray of your PC indicating an active Bluetooth service. If the computer of the user does not have an implemented Bluetooth functionality, a Bluetooth dongle can be used to establish the Bluetooth connection.

If the device is within 5 m from the Bluetooth, the computer will get into connection with the device via the TensioWin software.

2.4. Starting the device operation

To set up the device in operating mode, first check the power supply. The measurement protocol will be downloaded from the user's PC via Bluetooth communication.

Information about the status of the device and brachial blood pressure and heart rate values after a measurement appear on the LCD display.

The user can give four different commands to the device by one single button.

2.5. Functions of the button on the device

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

The voltage control of the batteries. The measured value appears on the display. The supply voltage is sufficient if the measured value is between 6.0 V and 5.4 V.

5.6V

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

LOw Batt

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

D 09-39

One short push of the button starts a manual measurement.

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

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

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

5.6V

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

CAL 0

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

87

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

CUFF

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

69

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

128/96

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

PUL 68

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

OFF

Two short pushes on the button (Pill): allows the patient to keep their "electronic diary" concerning taking their (antihypertensive) medication. After taking their medicine, two short pushes on the button stores the date and time in the memory. During a day, it is possible to store additional pill consumptions. By transferring all the data from the device to the physician's PC, he will be able to monitor the medication intake and therefore the adherence of the patient to the medication instructions.

Pill

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

FULL

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

D 09-39

N 20-39

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

OFF

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

2.6 Data transmission

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

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

- the diary of medication intake.

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

BLUELINK

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

CONNECT

2.7. Troubleshooting

The error codes, which appear on the display and their meanings, are described below. Please, note that you should not make any conclusions if an error appears only once because the movements of the patient and external factors can cause several types of errors. If the device cannot measure the blood pressure (e.g. because of movement), the measurement will be interrupted.

The meanings of the error codes shown by the device are as follows:

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

110	The measured result cannot be considered as a real blood pressure value because of some movement or arrhythmia
111	The brachial systolic blood pressure is higher than the maximum inflation level.
115	The heart rate cannot be considered as a realistic value.
116	Not enough evaluable systolic and/or diastolic values.

2.8 Sound signals

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

2.9 Using the device

- The programming and preparation of the device and reading the measured data out from the device are performed at a different time.
- The programming of Arteriograph24™ could be done by a person who is familiar with the use of the software of the device and have read the Instruction for use. However, the medical indication of the Arteriograph24™ measurement, and the evaluation of the obtained data can only be done by a physician.
- Choose the cuff with the proper size, as defined in subsection 2.2.
- Place the cuff on the right arm.
- Place the cuff with the tube exiting the cuff upward in the region of the brachial artery. Make sure that the hosing is in a position to allow unrestricted air flow.
- We recommend installing the cuff onto a thin, long sleeve shirt to increase comfort during wearing.
- The air connector of the cuff should be inserted into the air connector of the device (see figure 1).

  Attention! Please, take care of the connection of the air connector pair. You can connect it properly if you insert the plug with a twisting motion until a clicking noise can be heard.
- During measurements avoid any muscle movement, particularly in the arm, as this may lead to longer measurement or measurement errors, and it may decrease the accuracy of the measurement. The patient should remain still as the cuff started pressurization and should keep calm until the cuff is deflated. Avoid speaking and muscle movements.
- Ask the patient to keep a diary (daily activities, symptoms, the time of going to bed and waking up in the morning, the time of the medication intake, etc.)
- The extension of the duration of the Arteriograph24™ measurement series over 24 hours is rarely justified. Although the Arteriograph24™ is appropriate for longer (e.g. 48 hours) measurement period, but in this case the physician should evaluate the advantages and additive clinical value from the extended measuring period, compared to the inconvenience caused by the longer duration of the measuring process.

3. Specifications

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

3.1. Electromagnetic compatibility

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

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

Electromagnetic immunity

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

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

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

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

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

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

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

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

3.2 Use Specification

Intended medical indication	Non-invasive determination of brachial blood pressure, heart rate, and arterial function parameters of the patient intermittently throughout one or more days. The contraindications of use are defined in sections 1. and 1.4.
Intended patient population	Cannot be used on patients under 3 years of age. Clinically validated on a patient population above 3 years of age.
Intended part of the body or type of tissue applied to or interacted with	The cuff interacts with the skin surface of the upper arm. The cuff exerts pressure on the upper arm when inflated.
Intended user profile	Measurement schedule programmed and read from the instrument by the doctor or medical staff and measurements assessed by the physician. The device with a programmed measurement schedule is worn by the patient who may initiate some of the auxiliary functions of the device (eg. registering the time of medication intake). See sections 1. and 2.5. for details.
Use environment	Programmed and measurement results data read out in a medical environment, automatic measurements during the daily life (active and/or sleep periods) of the patients.
Operating principle	Oscillometric method

[redacted]

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