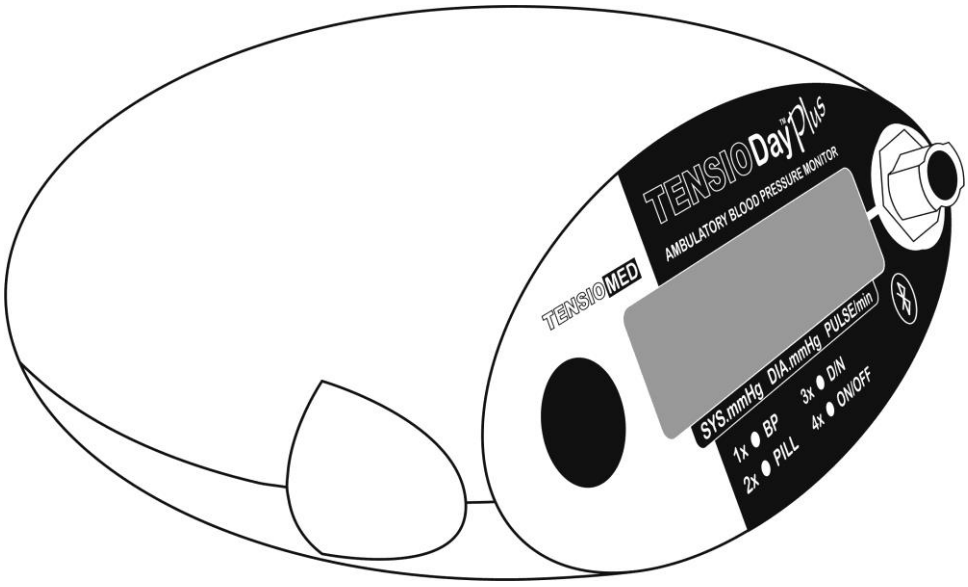
TENSIOMED®

TENSIODay™ Plus

Ambulatory blood pressure monitor
featuring central blood pressure measurement

User's Manual

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



With wireless communication

Bluetooth

CE 0197

TensioMed® TensioDay Plus-03v7-00
Revised: 31-05-2022

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1. Introduction and intended use of the device

Thank you for choosing TensioMed® TensioDay Plus ™.

The intended use of the device

The TensioMed® **TensioDay Plus™** device measures the brachial blood pressure, the heart rate, and the central systolic blood pressure intermittently throughout one or more days. The measurements are performed non-invasively using a brachial cuff.
The device with its adherent **TensioWin software** provides the values of brachial blood pressure, heart rate and central systolic blood pressure. It is plausible to use on those patients, where the information about aortic blood pressure is desired, but according to the physician's opinion, the risk of measuring these parameters by catheter and other invasive methods are higher than the benefit gained by knowing these parameters.
The Arteriograph24 is intended and validated for a **patient population of adults**.
The TensioDay Plus is a **multiple use device**. The device cannot be connected to any other instrument.
The TensioDay Plus is a professional medical instrument and cannot be used in a home environment, i.e., patients cannot use it on their own. The assessment of the measurement results requires extensive **medical knowledge**.
If the patient has a **pacemaker**, this does not affect the applicability of the TensioDay Plus.
If the patient's physiological functions are monitored with **other instruments** (e.g. ECG, respiratory rate, temperature, oxygen saturation), this does not affect the applicability of the TensioDay Plus. 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 TensioDay Plus 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 TensioDay Plus should not be performed.
The device is not recommended to be used in case of atrial fibrillation and 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 arrythmia do no influence the accuracy of the device.

*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.*

Regarding the 24-hour monitoring of blood pressure (ABPM), the limit values and application recommendations defined in the effective national and international hypertension methodological guidelines apply.
Despite intensive clinical research, the limit values and recommendations for the 24-hour monitoring of central blood pressure (SBPao, PPao) in methodological guidelines are not yet available, unfortunately.

The TensioDay Plus ™ instrument can be programmed with the TensioWin ™ software. The measurement plan is sent, and the blood pressure data is read back - from the doctor's computer or to the computer - via Bluetooth wireless communication between the device and the computer.
The automatic blood pressure measurement plan can be programmed for a maximum of 72 hours and a frequency of 10 to 90 minutes. Different measurement frequencies can be set for an “active” day, a “passive” night and for a so-called “special” period.
The measured values (systolic and diastolic blood pressure, heart rate, measurement date and exact time) are stored in the device's memory.
Regardless of the programmed measurement times, the patients can also initiate a manual measurement (e.g. if they have complaints, or they are unwell) by pressing the control button once. The device also stores all manually started measurements and this data is also displayed on the report.
Device reliability and data storage capacity provide increased adaptability for patients. The instrument can store 1000 data.

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

This Manual is produced on the assumption that the operator is an experienced user of the Windows 10 or 11 operating systems.
If the operator is not familiar with Windows operations, please refer to the online help of Windows or the Windows User Manual.

TensioMed® TensioDay Plus™ is an unregistered trademark of TensioMed Ltd.
Other company and product names mentioned herein may be trademarks of their respective companies.

1.1. Contents of the manual

This manual helps you in setting up and starting to use the TensioMed® TensioDay Plus™ device.

Please read this User Manual carefully before commissioning.

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

1.2. Supplementary Information and Helpful Hints

- This device does not produce electromagnetic disturbances during its operation and its immunity to the environmental disturbances is also good. The download of the measured data to the physician's PC is done by Bluetooth communication. The electromagnetic compatibility between the device and the PC is guaranteed. EMC classification: A.
- Regular service is recommended by an approved agent at least every two years to maintain optimum performance and accuracy.
- 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 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 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 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 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 next standard:
    - ISO 81060-2:2013 Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type

1.3. Warranty

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)

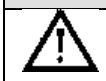
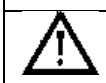
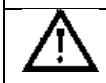
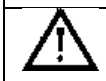
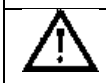
The instrument does not require regular maintenance during use. However, it is recommended that the instrument be sent to the service station (see below) of the manufacturer (TensioMed Ltd.) every 2 years for examination.

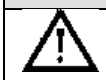
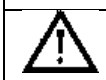
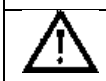
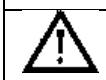
Attention! The procedures described above can only be performed by the manufacturer! If the operation of the device is faulty in any way, or it is due for supervision, please contact our customer service (contact information below). Please do not try to repair the device or have it repaired at any other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

Central office and service:
TensioMed Ltd.
97. Kossuth Lajos str.
Budapest H-1181
Hungary
Phone: +36 70 886 7337
+36 20 942 6049
Web: www.tensiomed.com
E-mail: info@tensiomed.com

1.4. General Information, warnings and precautions

We strongly suggest that you carefully study the Operating Instructions of this multipurpose blood pressure monitoring device and that you note the listed precautions. The TensioMed® TensioDay Plus™ can be used with 1.5 V long life batteries, size AA.

Attention!	
	**Attention!** If the device is not used for a longer period, 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 applying the ambulatory BPM device to patients with serious mobility or other impairments, also unconscious or otherwise incapable patients and patients with coagulation disturbances. For children it is also recommended to apply the unit with special care. Children should not use the device on their own!
	Do not remove the outer cover of the device! The TensioMed® TensioDay Plus™ 24-hour BPM device is sophisticated, multipurpose, software-controlled measuring apparatus. Should any operating problems occur, have the device serviced by the manufacturer's service department as described in section 1.3.
	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 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.
	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.
	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 subject.
	Too frequent or too long measuring periods might cause blood flow disturbances in the arm. Ensure by the proper programming of the device 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.
	In case 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 arm, 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. However, the validation of BP measurements of the device has not been done on preeclamptic patients yet.
	Do not use the device on neonates or infants! Cannot be used on persons below 3 years of age!

2. The TensioMed® TensioDay Plus™ device

2.1. Explanation of symbols

The front of the device is shown in Figure 1.

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

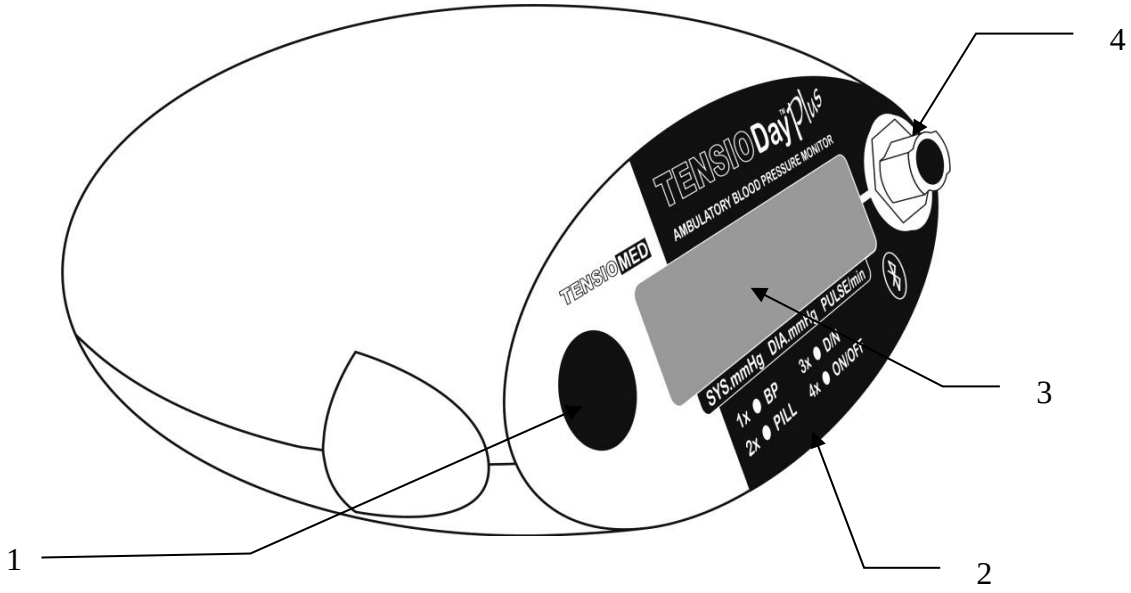


Figure 1.

The symbols on the bottom of the device are shown in Figure 2.

5 Name of the Manufacturer
6 The name of the device
7 The type ID of the device
8 The classification of the MDD requirements: II a
9 The nominal voltage range applicable with batteries
10 The classification of the protection against electric shock Classification: patient's side: CF.
11 Calling the attention to read thoroughly the present User's Manual
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 Head office of the 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 N_1N_2)
N_1=2: Protected against solid foreign objects of 12,5mm and greater
N_2=0: Not protected against water

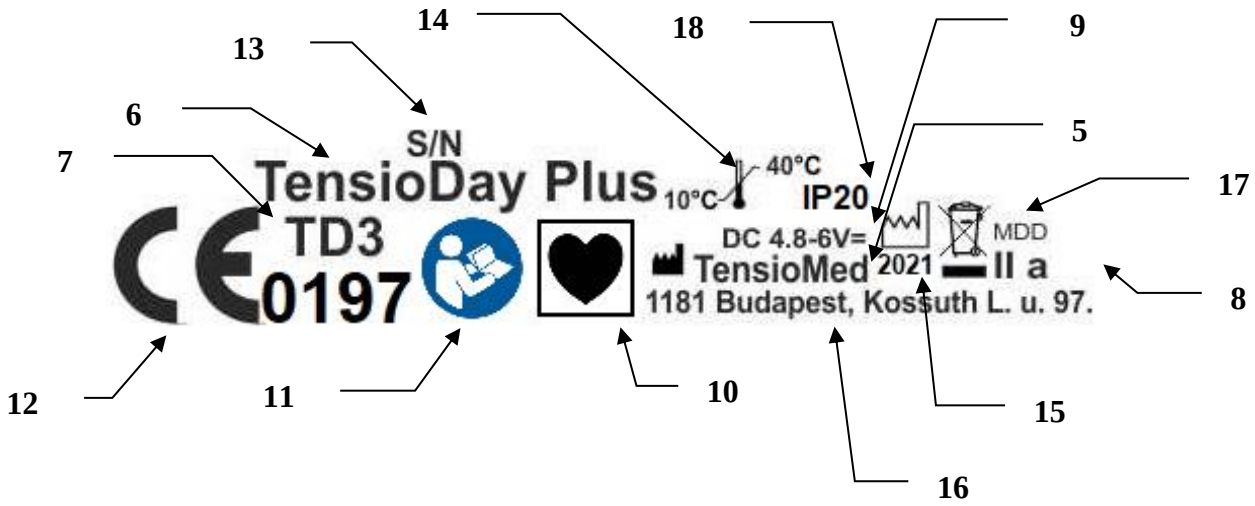


Figure 2.

2.2. Accessories

TensioMed® TensioDay Plus™ ambulatory blood pressure monitoring device (Figure 1), is supplied with the following accessories:

- 3 different cuffs
- TensioMed® TensioWin™ software on 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 2.4.5 for more information).

For the 3 different size cuffs the dimensions are:

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

Note: Correct cuff dimensions are important to achieve optimal performance and accuracy.

2.3. Installing the Device

TensioMed® TensioDay Plus™ is a battery operated device.

- Insert 4 durable alkaline AA batteries into the Device with taking care of the right polarity (see Figure 5)

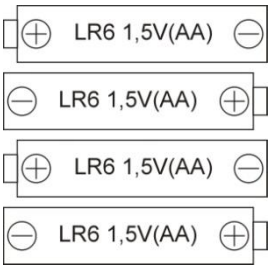


Figure3.

The clock circuits of the device are powered by a CR2032 battery, and it is continuously charged by the AA batteries, therefore the clock time is held and resetting the time is unnecessary between battery changes.
If you do not intend to use the device for a long period of time, 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 spent batteries immediately in an environmentally - safe way. The batteries and charging appliances have their own Instructions for use, we suggest you study them and follow manufacturers' guidelines.
In case you do not have a Bluetooth communication adapter or a built-in Bluetooth in your PC, connect the Bluetooth communication adapter to your PC and do the setting. If you find it necessary, ask for the help of your system supervisor who is responsible for your computer. Allow the Bluetooth communication in your PC. Then if the device is within 10 m from the Bluetooth adapter, the computer will get into connection with the device via the software. To transmit data, it is necessary to use the TensioMed® TensioWin™ program, of course.

2.4. Operation Instructions

To set up the 24-hour automatic BPM in operating mode first check power supply. The frequency of measurements will be downloaded from the physicians PC via Bluetooth communication.
To operate the device, there is one single button. The measured data and information about the status of the device appear on the LCD display.
The patient, by the one single button can give four different commands to the device.

2.4.1. Functions of the button on the device

After switching on, the device first performs the controlling measurement as follows:

5.6V

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.

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 computer time will be displayed. TensioMed® TensioDay Plus™ is ready for operation:

D 09-39

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

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

- the voltage of the batteries are checked (see adjacent figure)

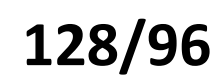
- calibration takes place, setting the zero pressure (see adjacent figure)

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

The device checks the placement of the cuff during inflating. 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 beeping signal. Check the cuff and its tightness and repeat the blood pressure measurement.

The deflation of the cuff is shown by the adjacent figure

After this process the device shows the systolic and diastolic BP values.



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

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

2.4.1.2. Two short pushes on the button (Pill): allows the patient to keep his "electronic diary" concerning taking his (antihypertensive) medication.
After taking his 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

downloading all the data from the device to the physician's PC, he will be able to monitor the medication intake and therefore the compliance of the patient.

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

FULL

2.4.1.3. 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** and by an **N** when the patient goes to bed.

D 09-39
N 20-39

2.4.1.5. By four short pushes on the button, the device can be switched off. You will see then “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

2.4.2. Data transmission

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

- the systolic and diastolic blood pressure values (mmHg)
- the pulse rate per minute
- 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 adapter is placed within the range of the device and it works - as its operation is permitted - the device and the PC will connect automatically. This sign will appear on the LCD. The actual data transmission does not happen, yet this can be started by the TensioMed® TensioWin™ program.

BLUELINK

During the operation of the Bluetooth communication between the device and the PC, when the actual data transmission is on, the following sign will appear on the LCD.

CONNECT

2.4.3. Error codes for users

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 once because the movements of the patient can imitate several types of errors. If the device cannot measure the blood pressure (e.g. because of movement), the measurement will be interrupted. With the TensioMed® TensioWin™ program - in case of a faulty measurement - it is possible to set the device to repeat it according to the measuring plan after 1 minute.

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 measuring time
3	The measurement was interrupted due to the weakness of the battery
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 BP measurement was not successful due to the failure of the device or the batteries are weak
100	The measured result cannot be considered as a real BP value or the patient has arrhythmia
101	The measuring circumstances e.g. the moving of the patient, disturbs the measurement
102	The device cannot sense the HR
110	The measured result cannot be considered as a real BP value because of some movement or arrhythmia
111	systole > max. inflation
115	The HR cannot be calculated or cannot be considered as a real HR value
116	Not enough evaluable results either from sys or from dia.

2.4.4. Sound signals

- If the device is working, beeping signals can be heard when pressing its button.

2.4.5. Usage of the device

- The programming and installation of the device, and the reading of the measurement data from the device is performed at different occasions. The assessment of the read data can be executed at a different time and location.
- The programming of the TensioDay Plus™ device can be performed anywhere. However, the establishment of the medical indication and the analysis of the measured data requires extensive **medical knowledge.**
- If the device is used for a normal blood pressure measurement, please prepare the patient according to the following procedure:
    - Perform the blood pressure measurement with the patient being in a sitting position. The patient shall sit comfortably, with both feet flat on the ground, with their arms and back supported, and not crossing their legs. Install the cuff on the upper arm of the patient, with a height of two fingers left free above the crook of the arm. Ensure that the midpoint of the cuff is at the height of the heart. Leave the patient in this sitting position for 5 minutes to rest. Ensure optimal temperature for the measurement and avoid loud background noises. The person performing the measurement shall sit beside the patient during the measurement.
- Select the proper cuff size, taking the following into consideration:
    - The bladder of the cuff used for the measurement shall have a length of at least 80% of the upper arm circumference.
    - The width of the bladder shall be at least 40% of the upper arm circumference.
    - Compliance to the latest blood pressure measurement guidelines is advised.
- Place the cuff on the non-dominant (less frequently used) arm of the patient, or that arm which had a higher blood pressure measured at a medical outpatient.
- Place the cuff with the tube exiting the cuff upward in the region of the brachial artery. Make sure that the hosing allows for free ambulation
- To avoid skin irritation a thin shirt might be used below the cuff
- The tube 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 cuff because it should not be too loose, it should not leak. You can connect it properly if you insert the plug with a twisting motion until it stops.**
- During measurements avoid speaking or any excessive muscle movement, particularly in the arm, as this may lead to longer measurement or measurement error and it may decrease the accuracy of the measurement. Please, suspend any activity for the duration of the measurement, if possible.

- Ask the patient to keep a diary on his/her daily activities, symptoms, and the time of going to bed and waking up in the morning.
- The extension of the measurement plan period of TensioDay Plus™ from one day to two or more days is very rarely justified. The device is capable of measuring for more than 24 hours (eg. 48 hours), but the decision to use this future requires careful consideration and assessment whether it is worth it to cause such a serious inconvenience for the patient to gain more clinical information.

3. Specifications

Power Source:
4 long life batteries, size AA
The mode to prevent electric shock:
The device is powered by inside, 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 v1.2, Class II, 115200 bps
PC interface:
Bluetooth communication adapter
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) measuring range:
30 - 280 mmHg; 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 TensioMed® TensioDay Plus™ TD3 device is intended for use in the electromagnetic environment specified below. The customer or the user of the TensioMed® TensioDay Plus™ TD3 device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The TensioMed® TensioDay Plus™ TD3 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	Class B	The TensioMed® TensioDay Plus™ TD3 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	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity			
The TensioMed® TensioDay Plus™ TD3 device is intended for use in the electromagnetic environment specified below The customer or the user of the TensioMed® TensioDay Plus™ TD3 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 TensioMed® TensioDay Plus™ TD3 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 TensioMed® TensioDay Plus™ TD3 device is intended for use in the electromagnetic environment specified below. The customer or the user of the TensioMed® TensioDay Plus™ TD3 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 TensioMed® TensioDay Plus™ TD3 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 *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 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 TensioMed® TensioDay Plus™ TD3 device is used exceeds the applicable RF compliance level above, the TensioMed® TensioDay Plus™ TD3 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 TensioMed® TensioDay Plus™ TD3 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 TensioMed® TensioDay Plus™ TD3 device			
The TensioMed® TensioDay Plus™ TD3 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TensioMed® TensioDay Plus™ TD3 device can help prevent *electromagnetic* interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TensioMed® TensioDay Plus™ TD3 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	0,12	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 *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 the central systolic blood pressure 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 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. 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 doctor. 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, 2.4.1.1., 2.4.1.2., 2.4.1.3., 2.4.1.4. and 2.4.1.5. for details.
Use environment	Programmed and measurement results data read back in a medical environment, automatic measurements during the daily life (active and/or sleep periods) of the patients.
Operating principle	Oscillometric method

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