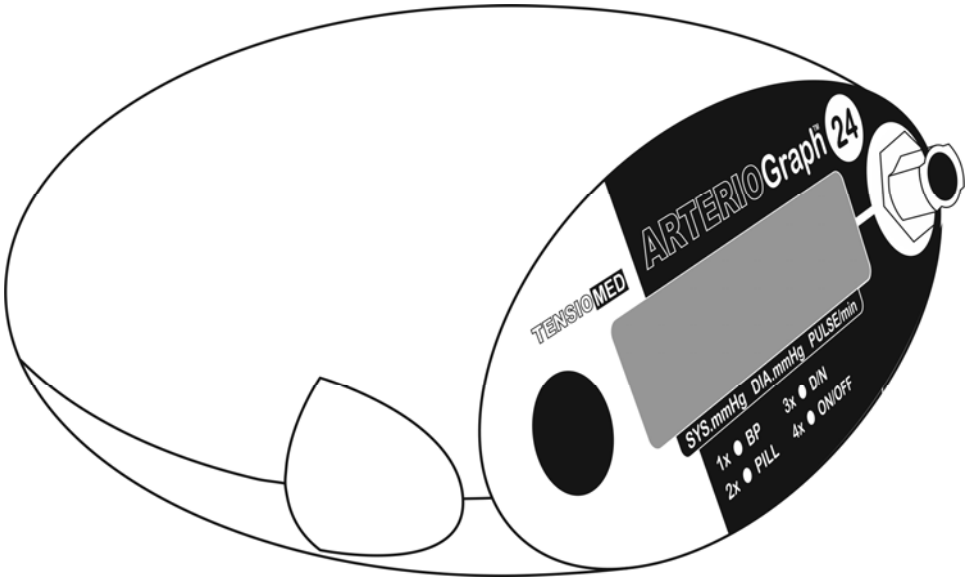
TENSIOMED®

ARTERIOGraph™ 24

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

User's manual

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



With wireless communication

Bluetooth

TensioMed® Arteriograph24™-5-02 v2.00.06
Revised: 21-11-2012

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1. Introduction

Thank you for choosing TensioMed® Arteriograph24™. The TensioMed® Arteriograph24™, is a professional device for the 24 hour monitoring of arterial function (stiffness) and peripheral blood pressure. For clinical and ambulatory requirements, Arteriograph24™ is validated according to the British Hypertension Society and the Association for the Advancement of Medical Instrumentation standards. The device uses oscillometric method for blood pressure determination. It can also be used for conventional home measurements, executed by the patients, offering a high level measuring quality and additional features.

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

Automatic measurements can be set for up to 72 hours, 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, namely the systolic and diastolic BP value, the pulse rate, the date and time of the measurement will be stored in the EEPROM of the device.

Apart from the programmed measurements, the patient may start a manual measurement (e.g.: he shows symptoms or feels sick). This can be done by a simple push button operation. All manually initiated measurements are stored and displayed on the software report.

The TensioMed® Arteriograph24™ can be used without the software program, for conventional, manually started BP home monitoring. The high accuracy of the measurements and the storage of the measured data offer greater flexibility. 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.

This Manual is produced on the assumption that the operator is an experienced user of the Windows XP/Vista/7 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.

TensioMed® Arteriograph24™ 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® Arteriograph24™ device.

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.
- The cuff and the Device itself can be cleaned with a wet cloth by making sure that no liquid enter into the Device or the cuff.
- The handling, storage, wrapping, substance-conservation and transportation of the producer's devices are defined in accordance with the general Quality Control Requirements.

1.3. Warranty

TensioMed Ltd undertakes 2 years of warranty for the device (12 months for the accessories). The repairs are done by TensioMed Ltd at the place below.

Head office and service:

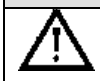
TensioMed Ltd.
2/e Kőér str.
Budapest H-1103
Hungary
Phone: (+36-1) 433 1700, 433 1701
Fax: (+36 1) 433 1709
Web: www.tensiomed.com
E-mail: info@tensiomed.com

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.

For optimum performance it is recommended to use Nickel-Metal Hybrid (Ni-MH) rechargeable batteries, or Nickel Cadmium (NiCd) rechargeable batteries, with1500 mAh capacity, size AA.

The TensioMed® Arteriograph24™ can also 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® Arteriograph24™ device is sophisticated, multipurpose, software controlled measuring apparatus. In case of any problem, turn to a qualified service.
	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.
	Do not disassemble the device.

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

2. The TensioMed® Arteriograph24™ 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

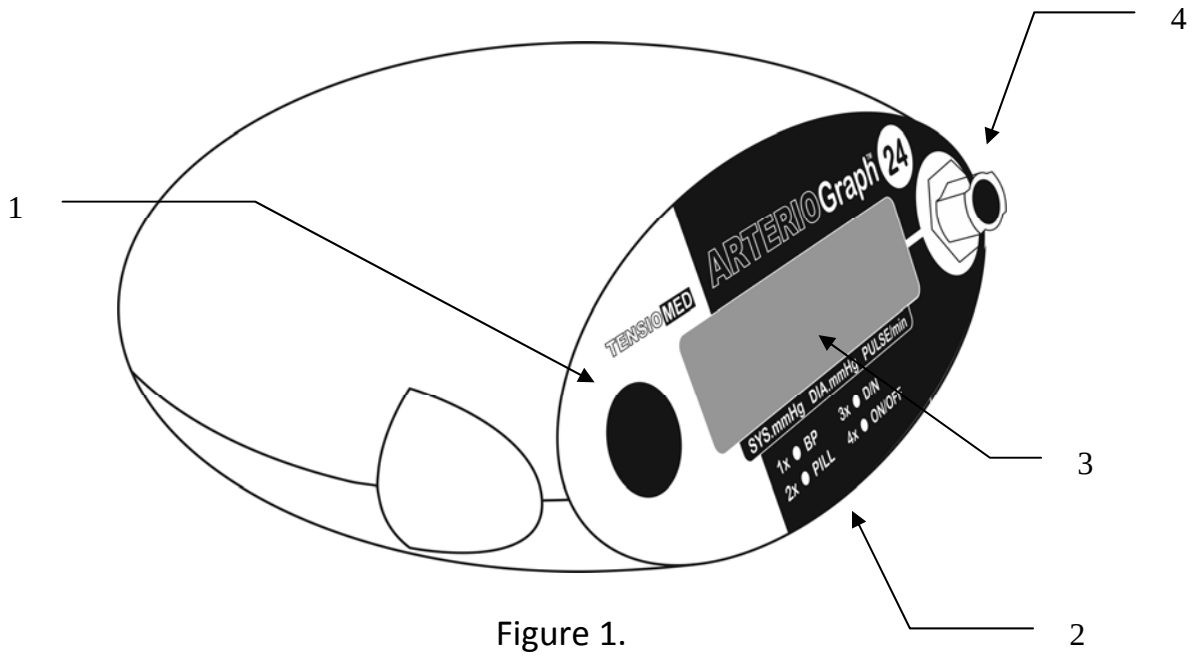


Figure 1.

The symbols on the bottom of the device are sown 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 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=2: Protection against vertically falling water drops when enclosure tilted up to 15°

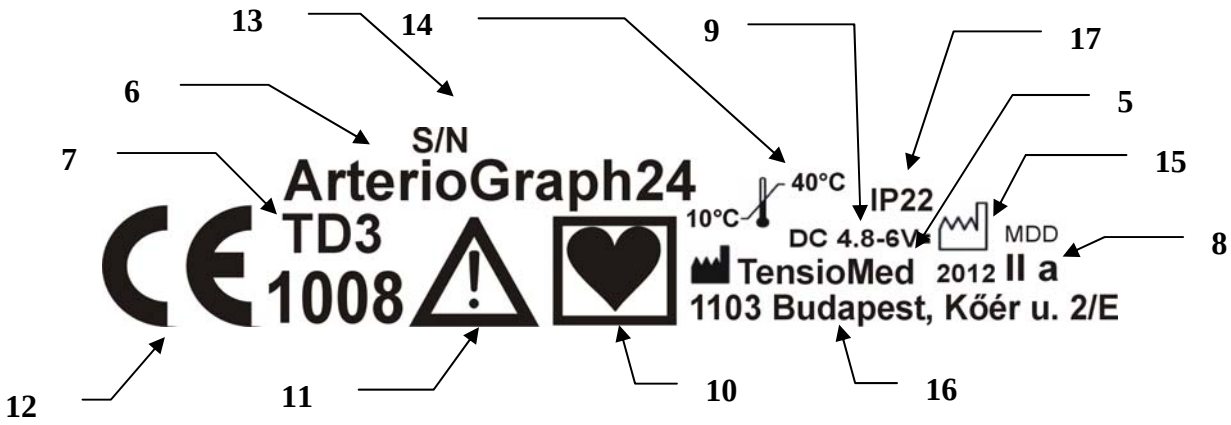


Figure 2.

2.2. Accessories

TensioMed® Arteriograph24™ device (Figure 1), is supplied with the following accessories:

- pouch for the device with belt
- four, AA size batteries
- 3 different cuffs
- TensioMed® TensioWin™ software on CD
- User manual
- Bluetooth adapter
- tape measure

For the 3 different size cuffs the dimensions are:

	Bladder Dimensions	Sleeve Dimensions	Arm Circumference
Cuff 01	34 × 8 cm	62 × 9 cm	>= 36 cm
Cuff 02	26 × 8 cm	52 × 9 cm	27 - 35 cm
Cuff 03	18 x 6 cm	38 x 7 cm	< 27 cm

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

2.3. Installing the Device

TensioMed® Arteriograph24™ 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.

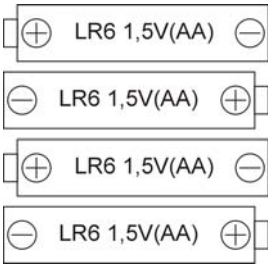


Figure 3.

The Ni-MH, NiCd batteries are rechargeable approximately one thousand times. If the capacity of the rechargeable batteries is low, it is shown on the LCD automatically. In this case please, change all the four batteries not only the ones you think are weak.

The clock circuits of the device are powered by a type Ni-Cd 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

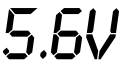
To set up the 24-hour automatic BPM in operating mode first check power supply. The frequency of measurements will be downloaded from the physicians PC via Bluetooth communication.

To operate the device, there is one single button. The measured data and information about the status of the device appear on the LC 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:



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 for alkaline batteries and between 5.2 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.

If the battery voltage is adequate, the device will be ready for measuring and the current computer time will be displayed. TensioMed® Arteriograph24™ is ready for operation:

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 the measurement 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.

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.

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 five 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.

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.

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.

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).
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. Using the device for ambulatory blood pressure monitoring

- place the cuff on the non-dominant arm
- 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 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
- 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

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 XP + service pack 3
Operating environment:
10 - 40 ° C
Humidity:
30 - 85 %
Size:
116,0 × 94,0 × 47,0 mm
Weight:
250g (including batteries)
Blood Pressure measurement method:
Oscillometric
Data Storage:
Max 1000 measurements
Blood Pressure measurements range:
30 - 280 mmHg
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 280 mmHg
Deflation:
Automatic, stepwise

3.1. Electromagnetic compatibility

Electromagnetic emissions		
The TensioMed® Arteriograph™ TD3 device is intended for use in the electromagnetic environment specified below. The customer or the user of the TensioMed® Arteriograph™ 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® Arteriograph™ 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® Arteriograph™ 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® Arteriograph™ TD3 device is intended for use in the electromagnetic environment specified below The customer or the user of the TensioMed® Arteriograph™ 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® TensioMed® Arteriograph™ 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® Arteriograph™ TD3 device is intended for use in the electromagnetic environment specified below. The customer or the user of the TensioMed® Arteriograph™ TD3 device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the TensioMed® Arteriograph™ TD3 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz – 80 MHz	3 V	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® Arteriograph™ TD3 device is used exceeds the applicable RF compliance level above, the TensioMed® Arteriograph™ 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® Arteriograph™ 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® Arteriograph™ TD3 device			
The TensioMed® Arteriograph™ 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® Arteriograph™ TD3 device can help prevent *electromagnetic* interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TensioMed® Arteriograph™ device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz – 80 MHz 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.			

TENSIOMED®