

TensioMed Ltd.

USER MANUAL

TensioDay
24 hour Blood Pressure Monitor

and

TensioWin
software

Type: TD2

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3. Specification

1.1. Purposes and function of the device

The TD2 type TensioDay, ambulatory blood pressure monitor is a professional device, for clinical and ambulatory requirements validated according to the British Hypertension Society and the Association for the Advancement of Medical Instrumentation standards. The device uses the 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.

TensioDay device is controlled by the TensioWin software. The measurement schedule and the blood pressure readings are loaded via infrared communication from and to the physician's PC, respectively.

Automatic measurements can be set for up to 48 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.

Four different types of blood pressure measuring plans with different measuring frequencies can be programmed even by pressing the button of the device without using a computer (see chapter 1.6.1/4). This measuring plan covers a 24-hour period from the time of programming.

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

The TensioDay can be used without the software programme, 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 500 measurements.

1.2. Important Information

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, with 1500 mAh capacity, size AA.

The TD1 can also be used with 1,5 V long life batteries, size AA.



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 the reach of children if it 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. It is also recommended the unit is applied with care to children. Children should not use the device on their own!



Do not remove the outer cover of the device. The TensioDay TD2 24-hour BPM device is a sophisticated, multipurpose, software controlled measuring apparatus. In case of any problems, turn to a qualified service.

1.3. Accessories

TensioDay ambulatory blood pressure monitoring device, shown on figure 1, is supplied with the following accessories:

- pouch for the device with belt
- charger, for AA size batteries
- four, AA size, rechargeable batteries
- normal adult cuff
- TensioWin software on CD
- User manual

Small adult (child) or large adult cuffs are also available. Dimensions are:

	Bladder Dimensions	Sleeve Dimensions	Arm Circumference
Normal adult (1312)	12,5 x 22,5 cm	16x52 cm	24-32 cm
Small adult (1314T)	6 x 28,5 cm	9x41 cm	24 cm
Large adult (1313)	14,5 x32 cm	16x70 cm	32-42 cm

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

1.4. Explanation of symbols

The front of the device is shown in Figure 1.

- 1 Device name
- 2 Function button (Offering five menu options, see section 1.6.)
- 3 Command symbols (see section 1.6.)
- 4 LCD Display.

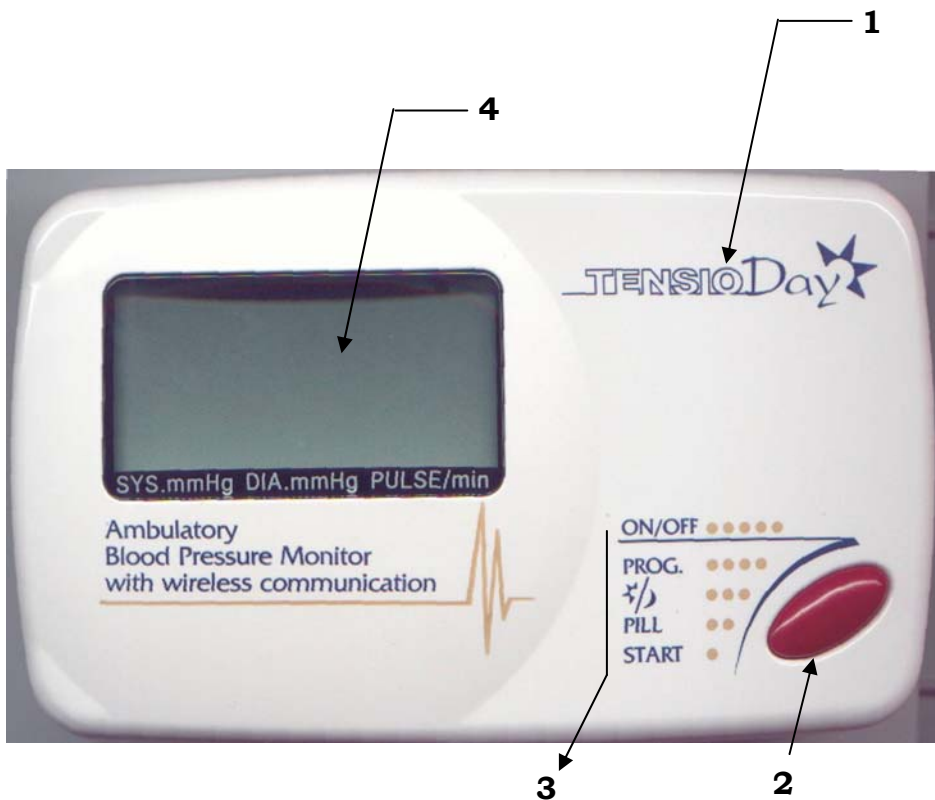


Figure 1.

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

- 5 The manufacturer's LOGO.
- 6 The name of the apparatus
- 7 The type number of the apparatus
- 8 The nominal voltage range applicable with batteries
- 9 The classification of the protection against electric shock.
Classification: patient's side: CF.
- 10 Calling the attention to read thoroughly the present User's Manual.
- 11 Certification mark guaranteeing that the apparatus complies with the prescriptions and requirements of the European Union.
- 12 Serial number.
- 13 Operating ambient temperature range
- 14 Year of the manufacturing
- 15 Address of the manufacturer

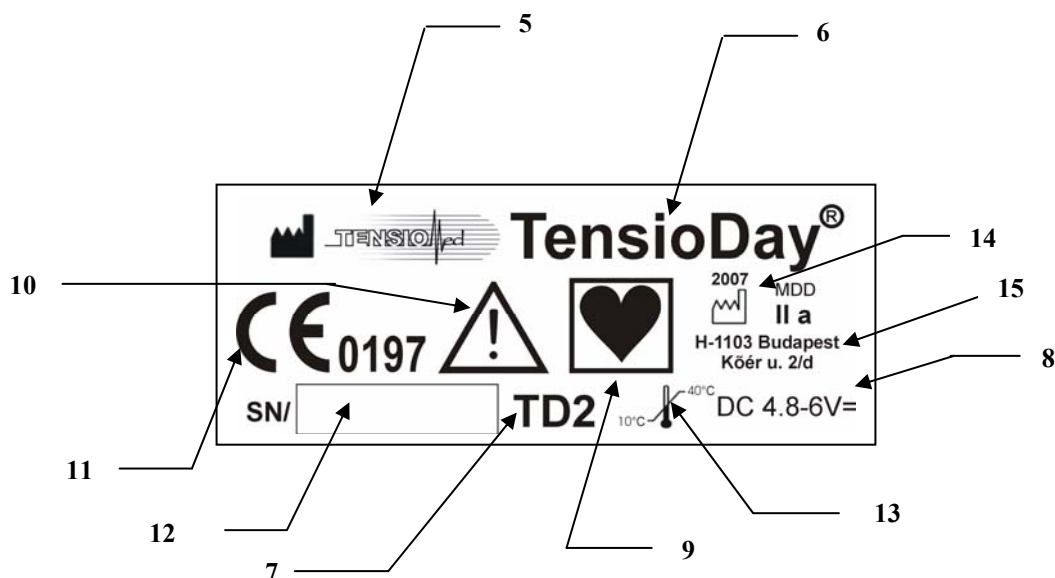


Figure 2

The side view of the device is shown in Figure 3.
16 window for the infrared communication.

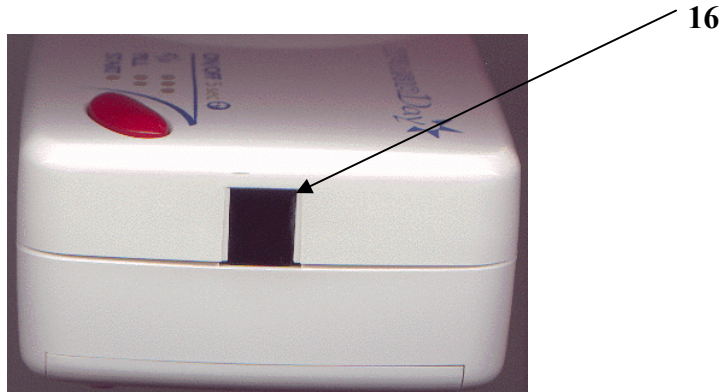


Figure 3.

1.5. Preparation to set up the device

TensioDay TD2 BPM device is powered by batteries.

- load the four size AA, Ni-MH or NiCd charged batteries into the device, with their polarity aligned
- Alternatively, insert four AA sized, long life batteries into the device as above
- TensioMed recommend the use of rechargeable Ni-MH or NiCd batteries with 1500 mAh capacity for optimum device performance
- The recommended chargers are: ANSMAN 4T2 or FRIWO

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 HA 35 storage 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 an infrared communication adapter or a built in infra port in your PC, connect the infrared 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. Set the data transmission speed at 19200 bps maximum. This can be set in the opening window of the operation program of the infrared adapter. Allow the infrared communication in your PC. Then if the device is within 1 m from the infrared adapter, it will get into connection with the PC automatically. However, to transmit data, it is necessary to use the TensioWin program, of course.

1.6. User's Instructions

To set up the 24-hour automatic BPM in operating mode first check power supply, (chapter 1.5.). The frequency of measurements will be downloaded from the physicians PC via infrared IrDA communication.

To operate the device, there is one single button (see chapter 1.4.). 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.

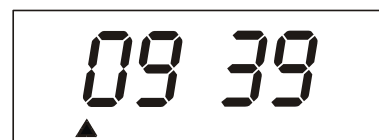
1.6.1. Functions of the button on the device

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. If the batteries are well charged, the measured potential will be between 5,4V - 4,4V. (The nominal potential is 4,8V)

If the voltage is under 4,4 V the batteries need replacing. The replace battery message will be displayed.

If long life batteries are used to power the device the measured nominal voltage will be 6V. The battery change symbol will be the same as above.

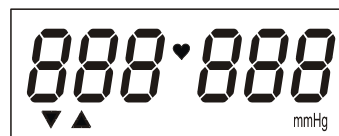


-If the battery voltage is adequate, the device will be ready for measuring and the current computer time will be displayed. TensioDay is ready for operation:

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 on the display and then:

- the test figure of the display comes into view (see adjacent figure)
- the voltage of the batteries will be checked (see adjacent figure)
- calibration takes place, setting the zero pressure (see adjacent figure)



After this, the measurement starts, by the inflation of the cuff, signalled 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 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. 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 consumption. By loading down 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.



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 triangle showing upwards and by a triangle showing downwards when the patient goes to bed.

4. By four short pushes on the button the BP measuring plan can be set without using a PC.

After the four short pushes, "Pr1" will appear on the display. If you press the button again for a short time, the device will store the measuring plan according to the 1st program. The device will indicate this by a short beeping signal.

If you do not press the button, the display will change to the next program after a short time, that is to "Pr2". The programs can be changed until the fourth one. The device will store that program as the BP plan at which the button is pressed. If you do not press the button at the programs, the device will get back to its

basic state, that is the time will be on the display again.

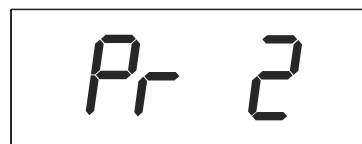
The time sharing of program 1:

Day period: at every 15 minutes
(between 6 and 22 hours)
Night period: at every 30 minutes
(between 22 and 6 hours)



The time sharing of program 2:

Day period: at every 10 minutes
(between 6 and 22 hours)
Night period: at every 30 minutes
(between 22 and 6 hours)



The time sharing of program 3:

Day period: at every 30 minutes
(between 6 and 22 hours)
Night period: at every 60 minutes
(between 22 and 6 hours)



The time sharing of program 4:

Day period: at every 20 minutes
(between 6 and 22 hours)
Night period: at every 40 minutes
(between 22 and 6 hours)



5. By five 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 would like 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.

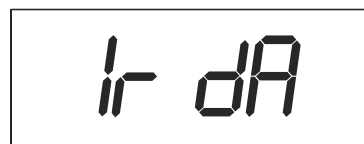


1.6.2. Downloaded data

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

- the systolic and diastolic blood pressure values (in 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 an infrared communication adapter is placed within the range of the device and it works, that is its operation is permitted, the device and the PC will connect automatically. This sign will appear on the LCD display. The actual data transmission does not happen, yet this can be started with the TensioWin program.

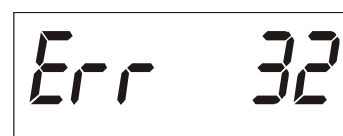


During the operation of the infrared communication between the device and the PC, when the actual data transmission is on, the following sign will appear on the LCD display.



1.6.3. Error codes for users

The error codes, which appear on the LCD display, and their meanings are described below. Please, note that you should not make any conclusions if an error appears once because the movement of the patient can imitate



several types of error. If the device cannot measure the blood pressure (e.g. because of movement), the measurement will be interrupted. With the TensioWin program it is possible to set that in case of a faulty measurement, the device would repeat it according to the measuring plan after 1 minute.

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

- | | | |
|--------------|---------------------------|--|
| 1 | "over the measuring time" | The device could not measure the patient's blood pressure within the measuring time. |
| 3 | "battery run down" | The measurement was interrupted due to the weakness of the battery. |
| 31 | "cuff missing" | The cuff is not connected to the device. |
| 32 | "cuff clogged" | The cuff tube is broken or something got into the tube (e.g. water). |
| 33 | "air leaking " | The cuff (or device) is leaking. |
| 34 | " cuff is not on the arm" | The cuff is not on the patient 's arm |
| 35 | "interrupted measurement" | The measurement was interrupted for some reason (e.g. because the patient pressed the button). |
| 90-99 | "device failure" | The BP measurement was not successful due to failure of the device or the batteries are weak. |
| 100 | "faulty result" | The measured result cannot be |

considered as a real BP value or the patient has arrhythmia.

110 “faulty result”

The measured result cannot be

considered as a real BP value.

112 “faulty result”

The measured result cannot be

considered as a real BP value or the patient has arrhythmia.

111 “faulty result”
113-114

The measured result cannot be

considered as a real BP value or the patient has tremor.

115 “faulty result”

The HR cannot be calculated or cannot

be considered as a real HR value.

101 “movement”

The measuring circumstances e.g. the

moving of the patient, disturbs the measurement.

102 “no detected pulse”

The device cannot sense the HR for

some reason.

1.6.4. Audible signals

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

1.6.5. 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 black opening on the left side of the device. 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, in particular in the arm, as this may lead to too long 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 (defined usually as the time of "lights off") and waking up (defined usually as the time of "lights on")

1.7. 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 to the physician's PC of the measured data is by optical, infrared communication. The electromagnetic compatibility between the device and the PC is guaranteed. EMC classification: A.
- It is recommended that an approved agent service the device at least every two years to maintain optimum performance and accuracy.
- The cleaning of the cuff is by wiping over with a damp cloth only.
- The handling, storage, wrapping, substance-conservation and transportation of the producer's devices are defined in accordance with the general Quality Control Requirements.

1.8. Useful addresses and telephone numbers

The TensioDay professional home blood pressure measuring device is produced and serviced by:

TensioMed Ltd.

H-1103 Budapest, 2/D Kőér utca

Telephone: +36 1 433 1700

Fax: +36 1 433 1709

E-mail: info@tensiomed.com

Web site: www.tensiomed.com

1.9. Warranty

TensioMed Ltd undertakes 2 years of warranty for the device (for the cuff we undertake only 6 months). The repairs are done by TensioMed Ltd at the above place.

2.1. The TensioWin software

TensioWin software has two main components:

- the first component is the patient and physician database. This database is similar in all TensioMed products, and allows for efficient patient management in a hypertension or cardiovascular clinic, for calculation of cardiovascular risk, and for printing consultation letters.
- the second component is specific for TensioDay and allows for programming of the device and for downloading and analyzing ambulatory blood pressure data.

2.2. Installation and start of the TensioWin software

Minimum System Requirements

- Pentium I. based IBM compatible computer with 32MB memory, 20MB free hard disk capacity, CDROM, 800*600 screen resolution,
- Windows 95 OSR2 operating system,
- Activated infrared port.

Installation

Insert the CD in your computer's CD ROM. The installation CD will start automatically. In case it does not happen, double click on the **setup.exe** file on the disc and the installation setup will begin. The installation process will offer you the default directory for the program. You can change this by using browse function. Wait until the files are copied to the directory. At the end of installation the TensioMed icon will be created and placed on your desktop.

The start of the program

You can start using the program by double clicking on the TensioMed icon. The devices of TensioMed are shown on the main panel. Select TensioDay and start the program by clicking on the figure.

2.3. Menus of the TensioWin software

The menus of the software are indicated by buttons on the screen:

1. Selection of the physician



By clicking on this button you can enter, edit, or delete physician data.

2. Selection of the patient.



By clicking on this button you can enter, edit, or delete patient data, calculate cardiovascular risk, and print office report.

3. Programming of the TensioDay.



This button allows you to prepare the blood pressure monitoring schedule and to download the plan to the TensioDay device.

4. Transfer data from the TensioDay



This button allows you to download the blood pressure data recorded by the TensioDay during the monitoring period.

5. Analyze data



By clicking on this button you can display blood pressure data in a tabulated or graphic format and see the statistical results.

6. Help



This function provides you help in using the software.

7. Setup



By clicking on this button you can send the following settings into the device:

- you can set that the target pressure of the device should be a determined starting value or 35 mmHg above the previous systole BP value
- you can set the threshold limits of target pressure
- you can determine the type of the cuff
- you can set that the device should repeat the faulty measurements
- you can either permit or withdraw that the placing of the cuff should be checked by the device or not
- you can download the actual date and time into the device
- you can change the language

These settings can be sent to the device by pressing the “Download into the device” button.

8. About



This function gives you information about the TensioWin software.

9. Time and date setup



By clicking on this button you can set the time and date of your computer.

10. Exit



This button exits the TensioWin software

11. Back



This button brings you back to the main panel of the TensioWin software and allows you to switch between devices

2.4. Using the TensioWin software

2.4.1. Physician's data

Selection of the physician

Select the doctor button. Find the physician in the list and by double clicking on the name or by clicking OK the physician will be selected. The name of the selected physician is indicated in the title row of the window.

Enter physician data

If you want to add a new physician to the database select New, and enter data of the physician in the window. Note that the fields in yellow have to be filled. Click OK to save the data. The name of the new physician now appears in the list.

Modify physician data

If you want to modify or edit previously entered data select Edit in the physician window. Once the modifications have been completed save your work by clicking OK.

Delete physician data

If you want to delete a physician from the list select the name of that physician in the window by clicking on it. The name will be highlighted. Press Delete. A communication window will ask you for confirmation of the deletion. Please note that deleted data can only be restored, by manually re-entering the data.

2.4.2. Patient's data

Selection of the patient

Once the physician has been selected, the name of the particular patient, who returned to the clinic or whose TensioDay is to be programmed, has to be selected. To do that, select the Patient button on the main menu. This will bring you to the list of the patients belonging to the physician selected previously. Find the patient in the list and select him by double clicking or by clicking OK. In the title row of the program window the name of the patient will now appear next to the physician's name.

Hint: you can search for a particular patient of the physician by using the search function. You can search for names or ID numbers. To search for a name check Name in the Search for field and start typing the name of the patient. The search commences with partially entered names.

Enter patient data

If you want to enter a new patient, select New in the patients window. The setup of the database corresponds to the steps of a usual outpatient visit. This allows for entering information on medical history, on current complaints, on examinations, on laboratory data and to assess cardiovascular risk. You can save data by clicking on OK. Please, note that the fields in yellow have to be completed. These comments or opinions are automatically added to the printed report.

Edit patient data

If the patient returns to the clinic for a follow up visit, or has new laboratory or blood pressure data, you can edit the patient database and prepare a follow up report. To do so, select the patient whose data you want to edit and click the Edit button.

In the “baseline symptoms”, “physical examination”, “office blood pressure” fields the current date will automatically displayed. Of course, you can review previous data by using the scroll bar. Only data entered to the last date will be printed in the report from this field. Clicking on the OK button can save modified data.

Allocate patients

You can allocate patients previously belonging to a particular physician to a new doctor. This may be necessary if, for example, one physician is being deleted from the database, but his patients will remain. The TensioDay device can only be programmed if the patient is belonging to a particular physician.

To allocate patients, first select the physician to whom new patients will be allocated. Then select the Allocate button in the physician window. This brings you to the list of patients, and allows you to select the name of the patient whom you want to allocate to the new physician, and then click allocate. The name of this patient will disappear from the list. Repeat these steps until all the patients have been allocated to their new physician. To leave the Allocate window click Back. By now the patients allocated to their new physician are listed under this physician's name.

Enter office blood pressure data

If you want to enter new office readings to a particular patient's database, select New on the Office BP panel on the Patient details window. Enter the systolic and diastolic blood pressure reading and the heart rate value then click OK. Entered values will be listed in the right panel with the date and time. Repeat these steps with each office reading. The average of the readings from the same date are automatically calculated and displayed on the bottom of the panel.

Delete office blood pressure data

If you want to delete previously entered office blood pressure data, first select the row you want to delete by clicking on it. These data will now appear in the left side of the Office BP panel. Delete these data by clicking delete.

Enter cardiovascular risk factors

The software allows you to enter clinical data that determine cardiovascular risk and to calculate this risk. Open the Patient details window of the patient to whom you want to enter cardiovascular risk factors and click on the Risk factors button. This brings you to the Cardiovascular risk factors window, where you can enter the data. Click OK to save the data.

Enter laboratory data

You can enter laboratory data of the patient in the Cardiovascular risk factors window. On the bottom of the window you will find prepared fields for entering some of the laboratory values. If you want to enter new data select the New lab data button in the laboratory data panel. Fill in the fields, and save data by clicking on the Save button. You can select the dimension of the values to be entered (e.g. mmol/l or mg/dl). After saving your work, the current date will be added to the panel. You can review previously entered laboratory values by clicking on the Previous lab data button.

Delete laboratory data

If you wish to delete a set of laboratory data, simply find the data by using the Previous- or Next lab data buttons and then click Delete. All laboratory data belonging to that date will be deleted.

Print patient data

You can print the patient data and the cardiovascular risk factors/laboratory data separately. To print the patient details click on the Print button on that window. A print preview of this page will be presented, with the most recent symptoms, physical examination and average office blood pressure results. Your comment or opinion entered under Opinion will also automatically be added to the printed page.

Print cardiovascular risk factors and laboratory data

Select the Print button on the cardiovascular risk factors window. A print preview of the page will be presented with the risk factors, laboratory data, and the estimated risk of cardiovascular disease in the next 10 years for the patient. The risk is calculated according to the equation derived from the Framingham study (Anderson KM. et. al. Cardiovascular disease risk profiles. Am Heart J 1990;121:293-8). The data needed to calculate risk are date of birth, sex, systolic blood pressure, current smoking status, diabetes, left ventricular hypertrophy detected by ECG, cholesterol, and HDL-cholesterol values.

2.4.3. Programming the TensioDay device

To set up a patient protocol and to program the device press the Program TensioDay button on the main menu. In the protocol set up window you can either select a pre-set monitoring plan for the ambulatory monitoring or create your own protocol.

The monitoring protocols are characterised by:

- the length of the test
- the **active** (awake), the **passive** (asleep), and (optionally) the **special** periods. This latter may be needed if there is a period of special interest (e.g. early morning hours before awakening) during which you want different measurement frequency
- the measurement frequencies during the active, passive (and, if included, special) periods
- the starting time of the test and the different periods

Pre-set plans are listed in the window. The first number in the name of the pre-set plan refers to the measurement frequency during the active, the second number to the measurement frequency during the passive, and the third number to the measurement frequency during the special period, respectively. The length of the planned monitoring is indicated by the number in brackets. Even when selecting a pre-set plan you can modify the length of the test, the start time of the test and the different periods, and measurement frequencies of the different periods. Measurements can be programmed up to 48 hours with frequencies from 10 to 90 minutes.

If you want to use monitoring schedules different from those listed in the pre-set plan window frequently, select New. This allows you to define new, customised protocols that you can program quickly later. When preparing a new pre-set plan you can define the length of the test and the measurement frequencies for the “active” daytime, “the “passive” night-time, and for an additional “special” period. Save the new pre-set plan by clicking OK after naming the new pre-set plan. The details of the new pre-set plan appear in the window.

You always can modify the starting time of the test.

Once the protocol is set click on the “Send” button. At this point the device’s infrared window has to face the infrared communicator of the PC. The Setup button on the main menu allows you to select the port to be used for the communication. Please, make sure that there is no obstacle in the infrared beam between the PC and the device and they are at the same level. The distance between the device and the infrared sensor should not be longer than 1 meter.

The process of download of the patient protocol to the device can be followed on the progress bar. The successful download is confirmed. The ongoing communication between the device and the computer can also be seen on the flashing red light of the infrared communicator and also on the display of the device that shows “CO PC” (see section 1.6.2.).

2.4.4. Transfer data from the TensioDay

If you want to transfer data from the TensioDay device into the computer select the “Transfer data from the device” button on the main menu.

Place the device with the infrared window facing the infrared communicating cable. The distance between the device and the infrared sensor can be up to 1 meter. The process of data transfer to the computer can be followed on the progress bar. The successful transfer is confirmed. The ongoing communication between the device and the computer can also be seen on the flashing red light of the infrared communicator and also on the display of the device that shows “CO PC” (see section 1.6.2.).

After successful data transfer the test are ready for analysis.

NOTE: You can transfer the blood pressure data any time during a particular ambulatory blood pressure monitoring test. This may be necessary, for example, if you want to check the performance of the device or see the blood pressure values while the test is in progress. The data transfer does not effect the set protocol, and after data transfer the test will resume until the set length of the protocol is completed. If you transferred data while the test was in progress, i.e. before the full length of the test was complete, this fact is shown in the Status window of the first page of the Analysis. If you transfer additional data from the same test (e.g. at the end of the monitoring) these new data will be appended to the partial results transferred previously to allow for complete data analysis.

2.4.5. Analysing data

To analyse ambulatory blood pressure monitoring data of a particular patient select the Analyse data button on the main menu. From the list of the tests belonging to that patient you can select the test to be analysed.

The analysis window has 7 pages:

The 1st page summarises the main characteristics of the protocol of the monitoring, and the status of the test.

For the purposes of analysis (graphic display and statistical analysis) you can redefine the start and end times of the active and passive periods even after the test is completed. This may be necessary as the actual sleeping and awake times of the patient during the test might be quite different from those originally planned during the protocol set up. If you modify the start and end time of the active and passive periods the graphic display and the analysis will be based on these modified periods.

The 2nd page is the tabulated list of the time, the date and the measurement data (blood pressure heart rate, pulse pressure). Readings above the threshold values are highlighted in red. Thresholds values, based on which some of the statistics are calculated, can be modified by clicking on the Blood Pressure threshold button in the right upper corner of each page of the Analysis window. The passive period is indicated by the shaded area and the special period by an “*” at the beginning of the row. The status column indicates whether a reading is result of an automated or manual measurement. The status column lists also the time of pill intakes and the time of waking up or going to bed. The comment column can be

used to type in comments to a particular reading (e.g. dizziness noted by the patient).

While the blood pressure measuring algorithm of the device automatically discards extreme blood pressure and heart rate values, the summary statistics is based on all data listed in this page. You can manually edit a particular reading by double clicking on that row. By doing so that reading will not be shown on the graph or included in the statistics. Double clicking again on a previously edited reading results in re-inclusion of that reading in the graph and statistics.

The 3rd page is the graphical display of the measurement data as a function of time. The set threshold values for the systolic and diastolic blood pressures for the active and passive periods are indicated by solid lines (note that you can modify both the threshold values as well as the start and end times of the active and passive periods). The pill intake is indicated by green circle on the top of the graph. There are several options for the graphic display:

- you can view either each individual measurement or the hourly averages
- the readings may be displayed either as individual bars or the systolic and diastolic values connected by a solid line
- you can have the comments typed in on the 2nd page be displayed
- you can have the mean arterial pressure for each reading be displayed
- you can view either the full test period or only a time segment of the test. Clicking on Time segment on the bottom of the page allows you to define the time segment to be displayed.

You can add the graph that is being displayed to the print list by clicking on the "+" button. To remove a graph from the print list click "-". Clicking on the printer sign shows you the print preview of that page.

The 4th page is a correlation plot of the systolic values as a function of the diastolic readings. You can display the plot separately for

- all data
- the active period
- the passive period
- the special period (only if there was one defined)

To select the data and the period to be printed click on the appropriate period in the Period window.

Similar to the previous page you can view the plot for either the full test period or only for a time segment of the test. Clicking on Time segment on the bottom of the page allows you to define the time segment to be plotted.

You can add the plot that is being displayed to the print list by clicking on the "+" button. To remove a graph from the print list click "-". Clicking on the printer sign shows you the print preview of that page.

NOTE: The summary statistics of the ambulatory blood pressure monitoring test is always printed on the same page as the correlation plot.

The 5th page allows you to view the histogram of the monitoring data. Similar to the previous pages, you can define which period to be analysed, and whether the full test or only a time segment is to be considered. You can select the systolic, diastolic, mean arterial pressure, or the heart rate data to be displayed. The displayed histograms can be added to and removed from the print list.

The 6th page gives you the summary statistics of the test. You can define which period to be analysed (active, passive, special), and whether the full test or only a segment of it is to be considered. The start and end time of the different periods can always be re-defined. Edited values are not included in the statistics.

The statistical summary includes:

- Mean
- Maximum and minimum
- Standard deviation
- Diurnal index (DI) that denotes the difference in mean blood pressure between the active and passive period, expressed as a percent of the mean pressure during the active period. If you re-define the start and end time of the active and passive period the value of DI changes accordingly.
- Percent time elevation (PTE) that denotes the length of time during the test the patient's blood pressure was above the threshold limits, expressed as percent of the length of the full test. The calculation assumes that the change in blood pressure between two readings is linear. If you re-define the threshold values, the PTE changes accordingly.
- Blood pressure load (Load) that denotes the area under the blood pressure curve exceeding the threshold limit.

You can add the summary statistics of the different periods or time segments to the print list. NOTE: each summary statistics will be accompanied by the corresponding correlation plot on the same page.

On the **7th page**, you can add your opinion to the selected examination. You can save your opinion by clicking on "Save". This opinion will be printed in the report.

2.4.6. Printing a report

There are two options for printing results:

First, on each page of the analysis window you can select the current graph for printing by clicking on the "+" button, display the print preview, and print that particular graph. The "+" button also adds that graph to your print list.

Second, clicking on the printer icon on the top of the Analysis window allows you to define the components of the full report and to print a full report. You can select or deselect the "Patient data", the "Cardiovascular risk factors/laboratory data", "Data", "Graph + statistics", "Histogram" or "Correlation" pages to be printed.

NOTE: you have to select the graphs, statistics to the print list separately to be included in the full report.

2.5 Forwarding a report by e-mail

It is possible with the TensioWin software to write a patient's full data relevant to a given examination into a file from the program's data base and send it in an e-mail to a certain address (with the general report in pdf. format) or to download a similar file into your program.

This function can be operated by clicking on the "@" button of the window introduced at the chapter "Analysing data". In case you use the function for the first

time, the program will offer you a registration window, in which the yellow fields must be completed because without knowing these data the e-mail cannot be sent. After completing the fields, the software will save the file or report containing the data of the given examination automatically and it will display the basic corresponding program of the Windows with the completed data.

If we receive a TensioDay-data file in an e-mail (*.tdf) and we would like to download it into our data base, it is enough to click on the attached file and we can see the examination data we received.

3. Specifications

Power Source:
4 rechargeable 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
Data Transmission:
Optical, IrDA, max. 19200 bps
PC interface:
Infrared communication adapter
Computer requirements:
Windows 2000 + service pack 4 / XP + service pack 2
Operating environment:
10 - 40 ° C
Humidity:
30 - 85 %
Size:
128x77, 5x45, 5 mm
Weight:
310 g
Blood Pressure measurement method:
Oscillometric
Data Storage:
Max 500 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:
Automatically controlled pump
Safety:
Maximum inflation 280 mmHg
Deflation:
Automatic
Working mode of the device:
Continuous