

The powerful software for
PC-supported blood pressure
monitoring and therapy monitoring.

BOSCH
+SOHN **boso**

PROFIL-MANAGER



Instructions for use
Installation guide

Compatible with
boso ABI-Serie | boso TM-Serie
boso medicus PC 2 | boso medilife PC 3



Version 6.3.0.107

CE 0124

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1 Scope of delivery

Content

1 Installation CD | 1 Instructions for use for boson profil-manager XD

Technical specifications

Minimum requirement for operation:

- 1GHz • 4GB RAM • 40 GB HDD hard disk
- USB 2.0 interface • Windows 8 • 1680 x 1050 Pixel

Accuracy of the displayed values:

Systolic, Diastolic, Pulse = Accuracy of the measuring devices used

Central blood pressure	= Systolic	Diastolic	MAP
Mean deviation	0.71	2.96	0.19
Standard deviation	5.95	5.21	3.78

ABI = Accuracy of the measuring devices used for the systolic pressure (2 digits after the decimal point)

PWV = $\pm 5\%$ (1 digit after the decimal point)

Icon explanation



Follow the instructions for use!



Observe the electronic instructions for use



Important notes/warnings



Switzerland - Authorisation

CE 0124 CE marking



Date of manufacture



Manufacturer



Unique product ID



Batch designation



Order number



Medical device

Intended purpose

Software for

- display of the measured values determined by boson measuring devices
- Calculation of mean values of the determined measured values in the form of statistics for blood pressure measurement
- Calculation of BMI
- Archiving of the measured values in a separate database
- Data exchange with practice EDP systems via GDT interface
- Programming of 24h measuring devices (TM-2430 / TM-2450) (interval limits, interval duration, maximum inflation)
- Control of ABI measuring systems (starting and stopping a measurement)
- Calculation of the ABI, in connection with the boson ABI system 100 (PWV)
- Calculation of the pulse wave velocity (PWV) in connection with the boson ABI system 100 PWV
- Central (aortic) blood pressure (cBP) calculation in conjunction with the TM-2450 (cBP)

Indication

The software is used to transmit, display, evaluate and archive measured values from the boson measuring devices and to calculate the parameters specified in the intended purpose.

Contraindication

The software must not be used to monitor vital physiological parameters, the change of which could result in immediate danger to the patient.

Intended users

The boso profil-manager XD is used by doctors or medical professionals trained in the use of the software.

Target patient group

The target patient group for the boso profil-manager XD depends on the respective devices whose measured values are transmitted.

1.1 Before installation

With the boso profil-manager XD, you have chosen software that can show you optimal results with a minimum training period. The boso profil-manager XD was deliberately built without the usual menu structure using individual tabs for control. For this reason, the individual windows and program parts, also referred to as registers, are explained in the instructions for use.

MD This software product is a medical product.



This software product may only be used for its intended purpose. This software product may only be used with boso devices or software that boso has recognised as compatible. Use of this software product for anything other than its intended purpose or in conjunction with incompatible software and/or incompatible devices could result in clinical misinterpretation, mistreatment/improper representation, and/or loss or corruption of patient-related data.



This document describes the most extensive configuration of the software product with the maximum number of options. Not all functions described may be available.

1.1.1 Backup

To prevent data loss, back up the file regularly "profman5.fdb" from the subdirectory C:\ProgramData\Boso\profmanXD\

1.1.2 Program operation

The program is operated with the mouse.



PC requirements

The computer used to evaluate the ABI/PWV measurement and cBP measurement must comply with the European standard EN 60601-1 in its currently valid version.

These instructions for installation and use for the boso profil-manager XD are valid from version 6.3.0.0; if there is current information, you will find it in the readme.txt file on the installation CD. The drive letters in these instructions for use are selected as examples:

C:\ for the local disk

D:\ for the CD/DVD drive

The path information corresponds to a standard single-user installation under the German Windows 10 (64-bit) operating system and may differ under other operating systems or language versions. Microsoft and Microsoft Windows are registered trademarks of Microsoft Corporation.

1.1.3 Network security, security and privacy

Customer responsibility for product security

As with any other computer based system, protection must be designed such that firewalls and/or other security devices are in place between the medical system (boso profil-manager XD & Firebird DB) and any externally accessible systems.

The customer is responsible for setting up and maintaining a secure and stable IT environment in accordance with general IT standards:

- Physical security (e.g. do not allow unauthorised persons to use the software product)

- Operational security (e.g. ensuring that sensitive data remaining on the system, such as exported files, is removed; deleting data that is no longer required; ensuring that the users of the software product do not leave the open system unattended)
- Procedural security (e.g. each individual user should be given a separate account for the practice/clinic computers; do not forget to remove an account that is no longer needed)
- Security policies (e.g. ensuring that the collected data and media of the software product are stored securely)
- Risk management
- Contingency planning

The practical implementation of technical security elements varies from location to location. A variety of technologies can be used for this purpose, including firewalls, virus scanners, anti-spyware software, authentication technologies, and network segmentation. Antivirus software is not included with the profil-manager XD. To protect stored patient data, bosso recommends running virus protection software on all product servers and all workstations. In addition, antivirus software should be kept up to date on all product servers and workstations.



bosso is not responsible for the installation or maintenance of antivirus software or for the integrity of a product system infected with a computer virus.

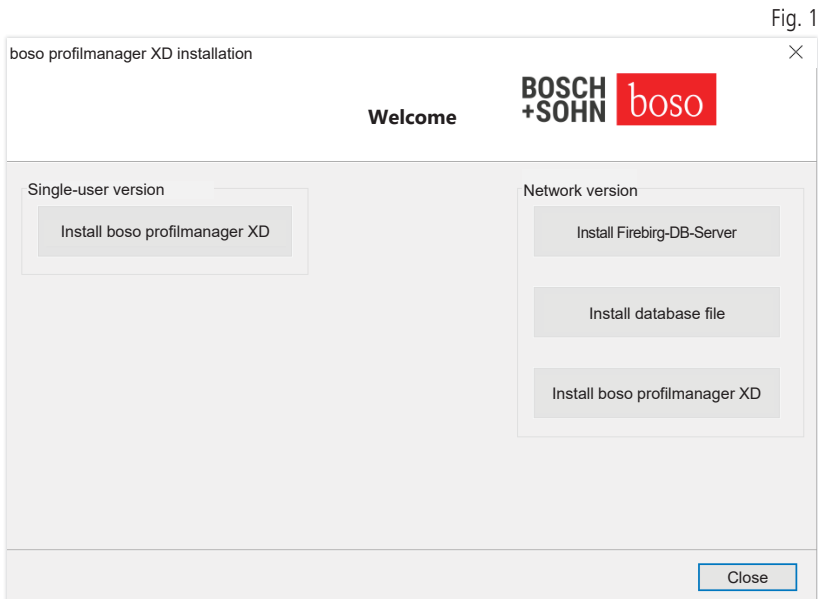
1.2 Installation of the boso profil-manager XD

To install the boso profil-manager XD, start the file D:\Bosolnst.exe manually or automatically using the autostart function after inserting the CD.



Make sure that you have administrator rights during the installation. (If in doubt, start the "Bosolnst.exe" program with the right mouse button and "run as administrator".)

Immediately after the start, the following selection screen appears:



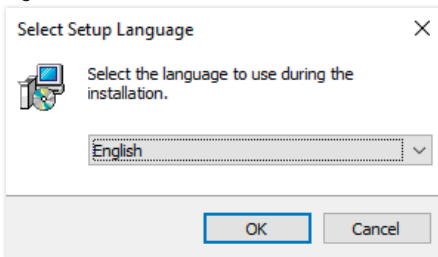
Choose between single-user version and network version.

1.2.1 Single-user version

The single-user version is used when the program is only to be run on one computer. In this case, no installation of a standalone Firebird database server is necessary (an embedded Firebird is used). Follow the installation wizard's instructions.

Choose your desired language for the installation:

Fig. 2

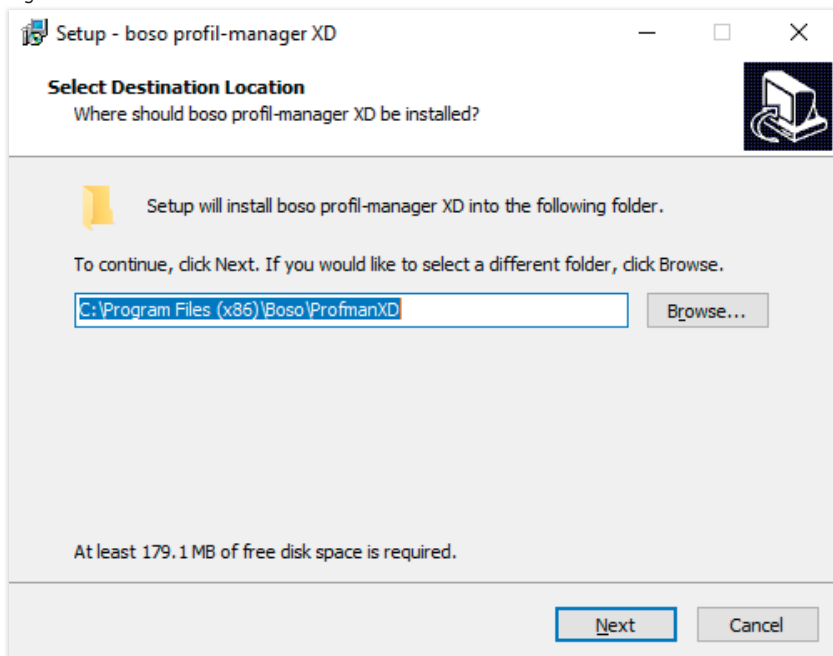


The following languages are also available:

- | | |
|------------|--------------|
| - German | - Slovakian |
| - French | - Finnish |
| - Italian | - Spanish |
| - Czech | - Hungarian |
| - Russian | - Slovenian |
| - Chinese | - Danish |
| - Croatian | - Polish |
| - Romanian | - Indonesian |
| - Estonian | - Swedish |
| - Serbian | |

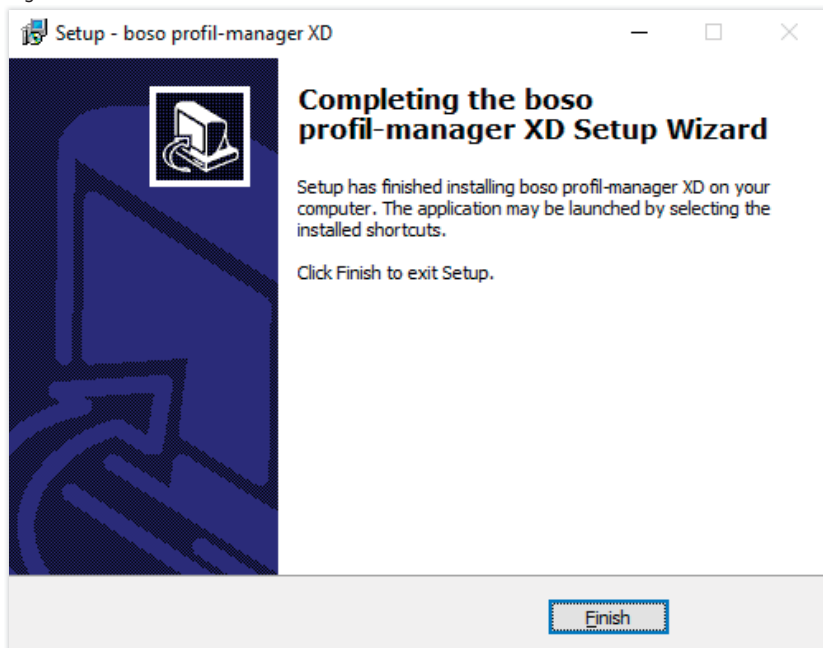
The target folder for the installation can be changed individually, but the default is usually used without changes:

Fig. 3



After successfully installing the boso profil-manager XD single-user version, close the installation wizard by clicking the "Finish" button.

Fig. 4



1.2.2 Network version

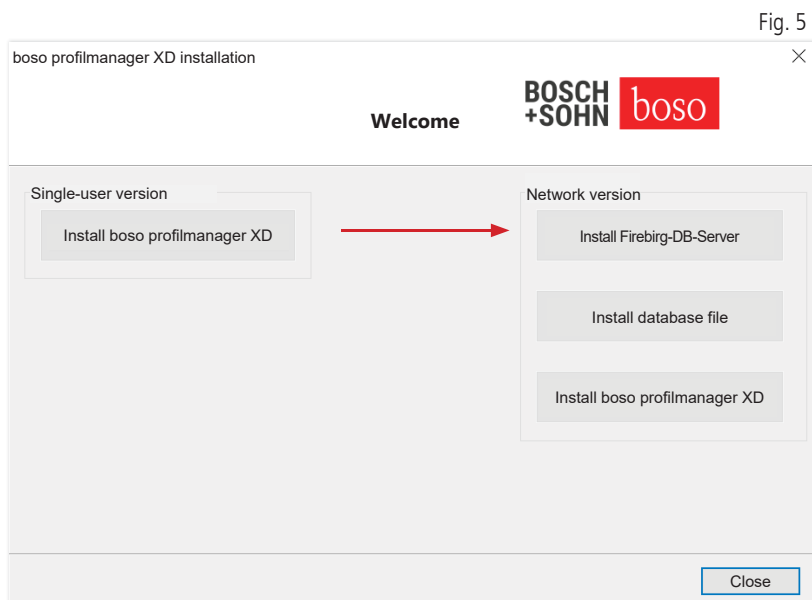
The network version is used when the program is to be operated on several workstations in the IT network.

The database can be installed anywhere in the IT network.

Installation on an IT network that includes other equipment may pose risks to patients, operators or third parties that were not previously known. The responsible organisation must determine, analyse and control these risks.

The following changes to the IT network could lead to new risks and therefore require additional analysis:

- Changes to the IT network configuration (e.g. updating the Firebird version, opening a TCP port, reconfiguring antivirus...)
- Connecting additional elements to the IT network
- Removal of elements from the IT network
- “Update” of devices connected to the IT network
- “Upgrade” of devices connected to the IT network



1.2.2.1 Installation of the Firebird database server

In order to be able to run the boso profil-manager XD in the network version, the Firebird database server must be installed on the computer on which the database is stored.

The Firebird database server installation is started with the “Install Firebird DB Server” button.



After selecting the language, follow the installation wizard and leave all the defaults unchanged.

1.2.2.2 Installation of the database file

The database file “profman5.fdb” can be stored anywhere on the network.



It should be noted that the computer on which the database is located must be running a current Firebird server from version 2.5, TCP port 3050 must be open for access if the firewall is active, and an antivirus programme must not block access to the database and the database server.

1.2.2.3 Installation of the boso profil-manager XD

The boso profil-manager XD is installed on any computer in the network using the “Install boso profil-manager XD” button.

Follow the installation wizard as described under [single-user version] in chapter 1.2.1.

1.2.2.4 Initial start-up of the network version

When you start the network version for the first time, a login window appears for the first login to the Firebird database (see Fig. 6).

Fig. 6

The screenshot shows a 'Login' dialog box with the following fields and values:

- Server name: server
- Database file: D:\Database\profman5.fdb (with a browse button)
- User name: sysdba (Default: sysdba)
- Password: masked with 10 dots (Default: masterkey)

Buttons at the bottom: Info, Login, Cancel.

The login data entered here are saved in the "profman.ini" file in the directory C:\Programs\Boso\ProfmanXD\ and can be adjusted at any time if necessary (e.g. if the database is moved to another location in the network).

Server name:

Name of the server on which the database is located.

Database file:



Drive, path and name of the boso profil-manager XD database file from the server's point of view.

User name:

Login information for the running Firebird database server. The default is "sysdba". If you already have a Firebird installation, the login information may differ.

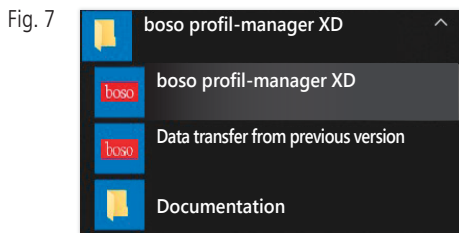
Password:


Login information for the running Firebird database server. The default is "masterkey". If you already have a Firebird installation, the login information may differ.

1.3 Data conversion from previous versions

To convert existing data from earlier Firebird databases, use the Converter.exe program.

Start the program either via the Windows Explorer from the directory path C:\Programs\Boso\ProfmanXD\ or via the Windows start button under the program group "boso profil-manager XD" the program "Data transfer from previous versions".



 The databases to be converted must be on the local system. Conversion over the network is not possible.

Enter the username and password to log in to the Firebird database server. The default values here are "sysdba" as user and "masterkey" as password.

Select the location of the boso profil-manager XD file in the "Target DB (profil-manager XD V 6.x)" field.

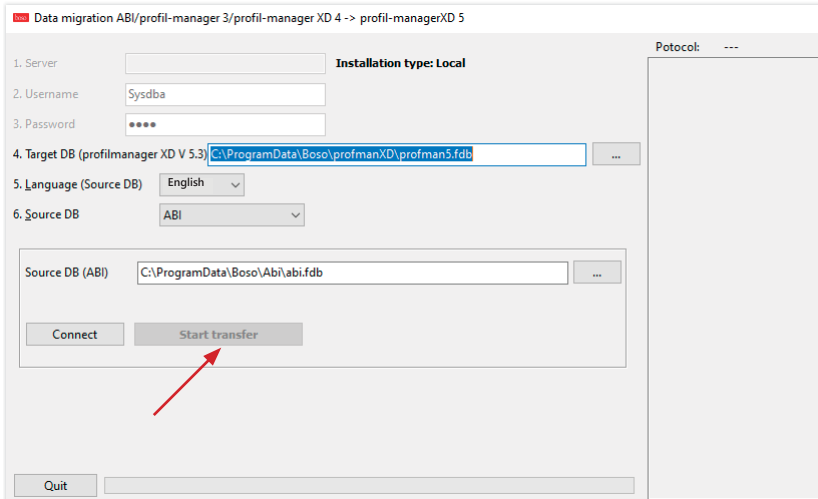
Choose the language of the source DB.

Choose the type of source DB (ABI, profil-manager 3, profil-manager XD 4.x, profil-manager XD 5.x).

Choose the location of the database to convert. Connect to the source database using the "Connect" button.

After successfully connecting to the source database, start the data transfer with the “Start transfer” button of the same name.

Fig. 8



If data is transferred from several databases one after the other, the data is merged in the new database.

The measurement data for a patient is only merged if the last name, first name and date of birth are identical. If the patient number differs, the patient number of the target database is retained.

If the last name, first name or date of birth do not match or if these fields have not been maintained, the patient is created anew. The patient number is retained unless it already exists in the target database, where a new patient number is generated.

All patients showing discrepancies are listed in a list. It is possible to maintain the data accordingly before the data transfer. Data that is not maintained will not be accepted.

1.4 Installation instructions

for USB cable for boso TM-2430 PC 2

The USB driver is pre-installed during installation (default). The USB connection cable supplied with the boso TM-2430 PC2 (see also the device's instructions for use) simply needs to be connected to a free USB port. The cable will now be recognised and installed automatically.



For boso TM-2430 PC 2: If the driver was not pre-installed, the file "dpinst_32bit.exe/dpinst_64bit.exe" (after installation in the directory C:\Programs\Boso\profmanXD\ftdi\)) is to be set as administrator and then the USB cable is connected to a free USB port.

1.5 Driver installation

for boso TM-2450 under Windows 8/8.1



Under Windows 8/8.1, this must be installed manually from the CD (D:\Drivers\TM2450\). Instructions for this can be found at: D:\Driver\TM2450\

1.6 Uninstall/Privacy

The product should be uninstalled after decommissioning. When uninstalling the single-user version, the database should be automatically deleted (C:\ProgramData\Boso\profmanXD\), so all patient data and measurement data is deleted.

When uninstalling the network version, the database must be deleted separately on the server.



The process cannot be reversed, all data (patient data and measurement data) from all application parts are irrevocably deleted.

For deleting a single patient, see 2.1.3.

2 Start

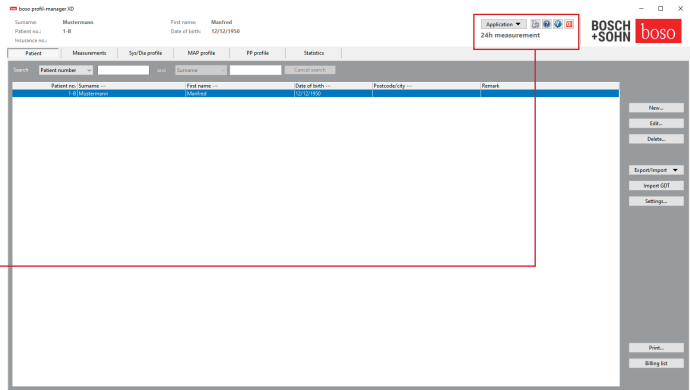


Fig. 9

After starting the profil-manager XD via the icon "boson profil-manager XD", select the program part according to the device application currently to be used:

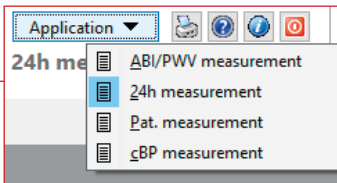



Fig. 10

Applications with already saved data are marked with the symbol "☰". Applications with no existing data are marked with the symbol "☐".

If you switch between applications with a selected patient, the "Measurement data" tab is automatically selected. In this way, measurement data from various applications provides a general overview of all of a patient's measurements.

Calling up the help function

By pressing the F1 key or the button  [Help] (see Fig. 9) these and other instructions for use can be called up in PDF format at any time. Please note that these electronically stored instructions for use are only up-to-date at the time the profil-manager XD is installed. You can always download the current instructions for use from the download area of our homepage.

Closing the help function

Obtaining the instructions for use in digital form

The instructions for use can also be accessed via the Internet.

Navigate to the following website: <https://www.boso.de/downloads>

Select the current version of the instructions for use there for download.

The PDF file is downloaded from the website and saved on your computer. The file can be opened with a PDF reader application. If you do not have a PDF reader installed, you can download Adobe Reader from the following website: <https://get.adobe.com/reader>

Getting more information about the software


By pressing the button  (see fig. 10) further information (UDI, version number, ...) can be called up at any time.

Fig. 11

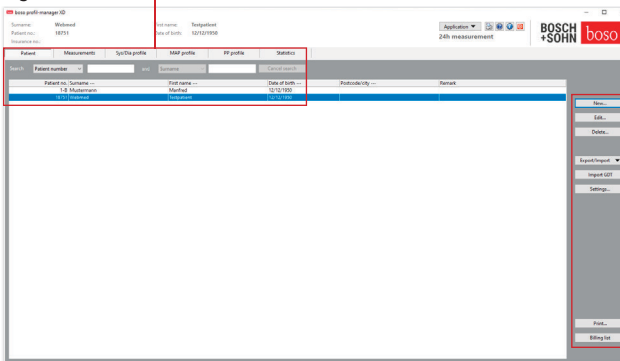


2.1 Patient tab

– valid for all applications

Patient	Measurements	Sys/Dia profile	MAP profile	PP profile	Statistics
Search	Patient number	and	Surname	Cancel search	
Patient no.	Surname	First name	Date of birth		
1-B Mustermann		Manfred	12/12/1950		
18751 Webmed		Testpatient	12/12/1950		

Fig. 12



The patient is selected by clicking on the desired patient. The patients can be sorted by clicking on the heading of the desired column. To restore the original patient number sorting, use the “Reset column order” function. To do this, right-click in the header line of the patient table. The “Search:” function can be used to search for names.

2.1.1 “New...” button

Creating a new patient. Name and patient number are mandatory fields. The patient number is specified by the system (consecutive number with the addition “-B”).

If you want to change the default patient number, proceed as follows: Hold down the “Ctrl” button on the keyboard and click on “Patient no.” with the mouse.



When operating in the practice environment, we strongly recommend that you only create new patients in the practice EDP.

2.1.2 “Change” button

Changing an existing patient’s personal information.

2.1.3 “Delete...” button (for a patient)



The process cannot be reversed, all data (including measurement data) from all application parts are irrevocably deleted.

2.1.4 Export/Import button

2.1.4.1 “Export Excel”

“Export Excel” (see Fig. 12) exports the data of the currently selected patient (from the current application ABI, 24h, patient measurement) in Excel-readable .xls format. File name and storage location can be freely selected.

2.1.4.2 “Export patient (XML)”

“Export Patient (XML)” (see Fig. 12) exports the data of the currently selected patient in profil-manager XD readable .xml format.

The transfer path is used from the settings of the transfer files for integration into the practice EDP (see next chapter “Settings...” button). The file name is made up of the active application and the patient number.

Example “2430_10.xml” stands for the patient data of the patient with the patient number 10 from the 24h measurement application.

2430_#.xml stands for the data from the 24h measurement

ABI_#.xml represents the data from the ABI measurement

medicus_#.xml stands for the data from the patient measurement

medicus_#-M.XML stands for the data from the bosso app

2.1.4.3 “Import patient (XML)”

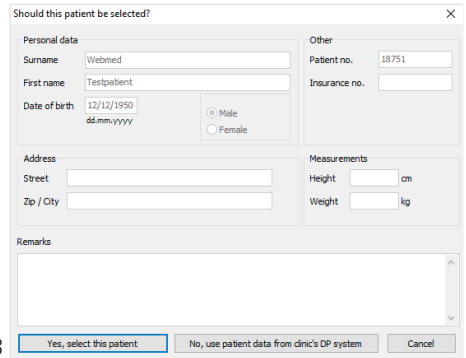
“Import patient (XML)” (see Fig. 12) imports the data of a selected patient, e.g. from the bosso app. The displayed patient is selected with the “Yes, select this patient” button.



With the “No, use patient data from the practice EDP” button, all existing measurement data is assigned to the patient from the practice EDP.

2.1.5 Import GDT

The GDT import file, if available, is read in and the patient it contains is selected or created. If a patient with the imported patient number already exists, the following mask is displayed:



The dialog box titled "Should this patient be selected?" contains the following fields and controls:

- Personal data:**
 - Surname: Webmed
 - First name: Testpatient
 - Date of birth: 12/12/1950 (format: dd.mm.yyyy)
 - Gender: Radio buttons for Male (selected) and Female.
- Other:**
 - Patient no.: 18751
 - Insurance no.:
- Address:**
 - Street:
 - Zip / City:
- Measurements:**
 - Height: cm
 - Weight: kg
- Remarks:** A large text area for notes.
- Buttons:** "Yes, select this patient" (highlighted), "No, use patient data from clinic's DP system", and "Cancel".

Fig. 13

2.1.6 "Settings ..." button (see Fig. 12)

Since the settings are application-specific, they are explained in the application chapters (chapters 3-5) (see Fig. 12).

2.1.7 "Print..." button (see Fig. 12)

Printout of the patient data appears on the screen. The data can then be printed out via the selected printer (see Fig. 12).

The Windows standard printer is the default for paper printing.

If "PDF file" was selected in the print settings, a PDF file is created. The file name of this PDF file is pmXD_pat#.pdf.

pat# = Patient number

2.1.8 "Bill list" button (see Fig. 12)

Generation of an overview list that can be limited in terms of the number of measurements carried out for the currently selected application (not available for patient measurements).

For example, for a simple overview of how many 24h measurements were carried out in the first quarter (see Fig. 12).

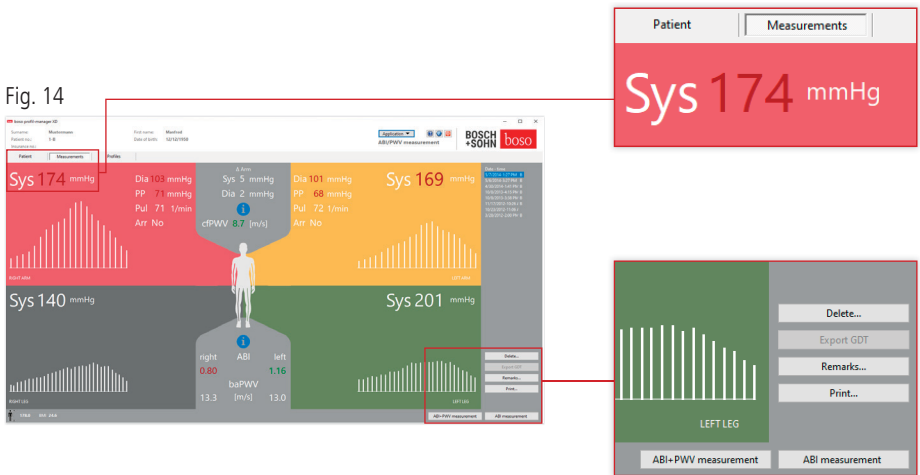
If "PDF file" was selected in the print settings, a PDF file is created. The file name of this PDF file is pmXD_cl.pdf.

3 “ABI/PWV measurement” application

3.1 “Patient” tab

See section “2.1 Patient tab - valid for all applications”.
“Settings” button see chapter 3.4.

3.2 “Measurement data” tab



In the “Measurements” tab, measurements that have been carried out can be viewed and new measurements can be carried out. To view ABI/PWV measurements that have already been taken, select the desired ABI/PWV measurement in the “Date - Time” field.
The following parameters are displayed in the screen display (each for the left and right half of the body):

Sys Systolic blood pressure of the upper arm, shown in red >140 mmHg

Dia Diastolic blood pressure of the upper arm, shown in red > 90 mmHg

PP Pulse pressure = difference between systolic and diastolic, shown in red >54 mmHg

Pul Heart rate in bpm

Arr Indication of whether there was an irregularity in the pulse rate of more than 25% during the measurement, shown in red if an arrhythmia is present

ABI Ankle-brachial index = quotient of the systolic pressure of the leg measurement and the higher systolic pressure of the arm measurements, shown in red for ABI < 0.9 [default]

baPWV (optional) measured pulse wave velocity upper arm-ankle (brachial-ankle). Since there is no exact limit value, but only a grey area of 14 to 18 m/sec, the baPWV value is only displayed in neutral black.

In some cases, the limit value is also set individually depending on the patient's gender, age and blood pressure.

cfPWV_calc (optional) carotid-femoral pulse wave velocity calculated from the baPWV, shown in red ≥ 10 m/s (no display if both ABI values < 0.9)



Since body height is required to calculate the PWV, it must be entered.

Sys Systolic blood pressure at the ankle

Diff Arm Sys Difference between the systolic values from the left upper arm to the right upper arm, shown in red > 10 mmHg

Diff Arm Dia Difference between the diastolic values from the left upper arm to the right upper arm, shown in red > 10 mmHg

By clicking on one of the oscillation profiles, the selected profile is displayed larger. The "Pulse level over time" tab shows the oscillation progression over the time axis. The "Pulse level via cuff pressure" tab shows the oscillation progression via the cuff pressure.

3.2.1 "Delete..." button (see Fig. 14)

Measurements that have already been carried out are irrevocably deleted.

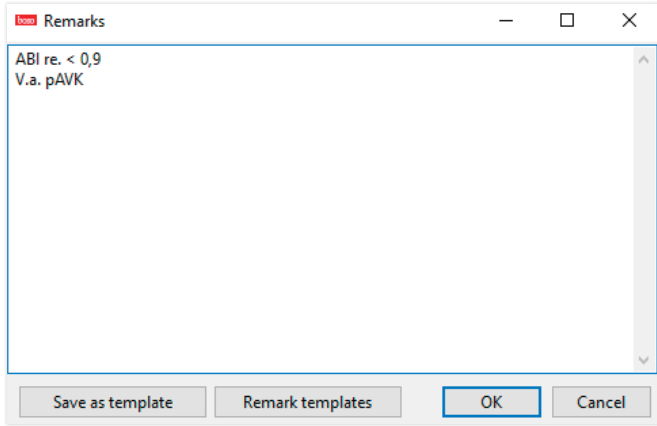
3.2.2 "Export GDT" button (see Fig. 14)

Manual generation of the GDT export file. Only available with previous GDT import of the active patient (see Fig. 14).

3.2.3 “Remarks...” button

A remark can be added to a measurement with a mouse click (or via the button (see Fig. 14)) in the “Remark” field.

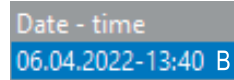
Fig. 15



Recurring remarks can be saved as a template using the “Save as template” button. Saved remark templates can be easily inserted into a remark field at any time using the “Remark templates” button.

Measurements with remarks are marked with a “B” in the “Date - Time” field:

Fig. 16



3.2.4 “Print...” button (see Fig. 14)

Generates a printout of the current measurement.

If “PDF file” was selected in the print settings, a PDF file is created. The file name of this PDF file is ABI_pat#_YYYYMMDD_HHMMSS_m.pdf (see Fig. 14).

pat# =	Patient number
YYYYMMDD_HHMMSS =	Date and time of the measurement
m =	Identification letter for measurement

3.2.5 “ABI measurement” button (See Fig.14 below)

Performs an initialisation of the boso ABI system 100 and starts a new measurement. A running measurement can be cancelled at any time using the “Cancel measurement” button or the STOP button on the device. After completing the measurement on an extremity, the “Save measurement” button becomes active. The measurement could already be saved now (e.g. if an extremity is missing).

When all four extremity measurements are complete, the active “Save measurement” button will be outlined in green. The measurement is completed successfully and can be saved then.

If an error occurs during a measurement, this is displayed in the respective measurement window:

(82) Measurement error/no measured value displayed -> Repeat measurement



If no measurement result is displayed for the blood pressure, check the cuff and hoses, then carry out a repeat measurement. If no measurement result is repeatedly displayed, this can indicate a circulatory disorder or media sclerosis. Further investigations are recommended here.

(83) Connect cuff

(89) System error -> Device should be checked by the manufacturer’s service department

3.2.6 “ABI/PWV measurement” button

(Optional - see Fig.14 below)

Automatically performs a PWV measurement 10 seconds after the completion of the ABI measurement described in 3.2.5.

When the PWV measurement is complete, the “Save measurement” button will be outlined in green. The PWV measurement is then successfully completed and can be saved.

3.3 “Profile” tab

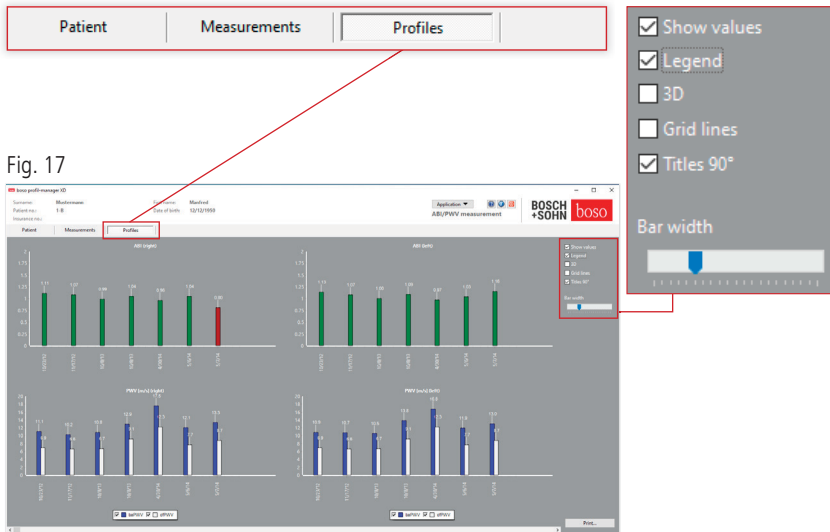


Fig. 17

In the “Profile” tab, the (optional) ABI/PWV values of all measurements are displayed graphically as bars. The ABI colour representation corresponds to the setting under “Assessment” (red: ABI < 0.9).

The profile display can be optically adjusted by various parameters:

Show values (default): ABI values are shown above the bars.

Legend: The legend for the measured values is displayed in the diagram.

3D: The bars are displayed in 3D optics.

Grid: Grid lines are drawn in the coordinate system.

Labelling 90°: The x-axis label is rotated by 90°.

3.3.1 “Print...” button (see Fig.17)

Generates a printout of the profile display. If “PDF file” was selected in the print settings, a PDF file will be created. The file name of this PDF file is ABI_pat#_p.pdf.

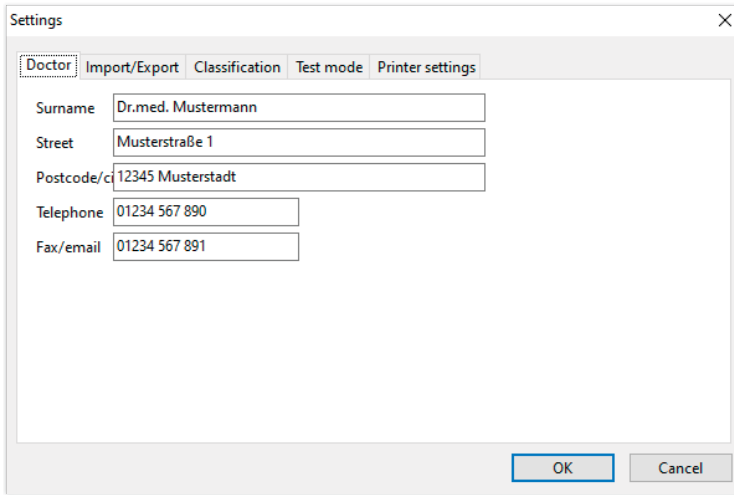
pat# = Patient number

p = Code letter for profile

3.4 “Settings” button in the “Patient” tab

3.4.1 “Physician” subtab

Fig. 18



The screenshot shows a 'Settings' dialog box with a close button (X) in the top right corner. The 'Doctor' subtab is selected, and the 'Physician' subtab is active. The form contains the following fields:

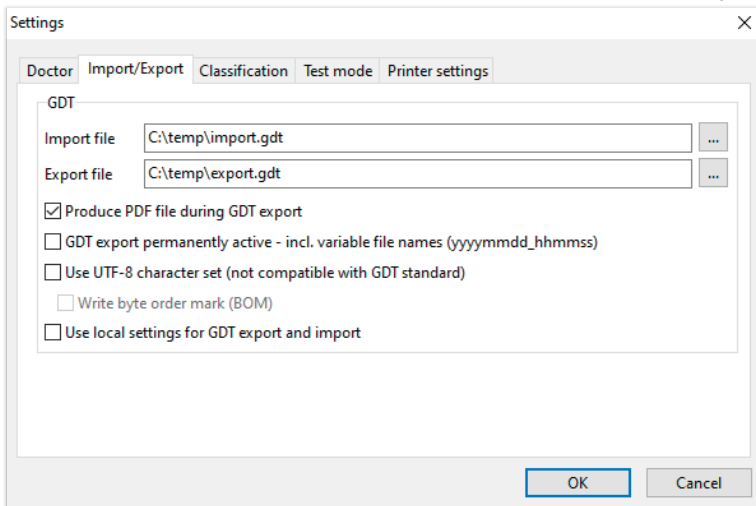
Surname	Dr.med. Mustermann
Street	Musterstraße 1
Postcode/ci	12345 Musterstadt
Telephone	01234 567 890
Fax/email	01234 567 891

At the bottom right, there are 'OK' and 'Cancel' buttons.

In the “Physician” subtab, the personal data of the attending physician is entered as the basis for the footer in the printout.

3.4.2 “Import/Export” subtab

Fig. 19



The screenshot shows the 'Settings' dialog box with the 'Import/Export' subtab selected. The 'GDT' section is expanded, showing the following options:

- Import file: C:\temp\import.gdt
- Export file: C:\temp\export.gdt
- Produce PDF file during GDT export
- GDT export permanently active - incl. variable file names (yyyymmdd_hhmmss)
- Use UTF-8 character set (not compatible with GDT standard)
 - Write byte order mark (BOM)
- Use local settings for GDT export and import

At the bottom right, there are 'OK' and 'Cancel' buttons.

When using a practice EDP that supports the GDT interface, the path and file names for the export or import file are specified here. The buttons next to the input fields for the import and export file give you direct access to the Windows directory structure.

Example: c:\prax_edv\import.gdt

Import file = Export file of the practice EDP

Export file = Import file of the practice EDP

The GDT import takes place automatically when the program starts or manually by clicking on the "Export/Import -> Import GDT" button if there is a valid GDT import file in the specified directory.

The GDT export only takes place if the patient imported from the practice EDP is active. The export takes place automatically when the program is exited (provided measurement data was read in from the device during the current program session) or manually at any time by clicking on the "Export GDT" button in the "Measurement data" tab.



The data export is deactivated if the patient has changed after the automatic import. It will be reactivated when that patient is re-selected. The data export is also deactivated if no import has previously taken place.

For certain applications (connection to HL7 in hospital operations) it may be necessary to permanently activate the GDT export and to name the export file variably (Export.gdt -> yyyyymmdd_hhmmss.gdt). For this, the option "GDT export permanently active – including variable file names" must be activated.



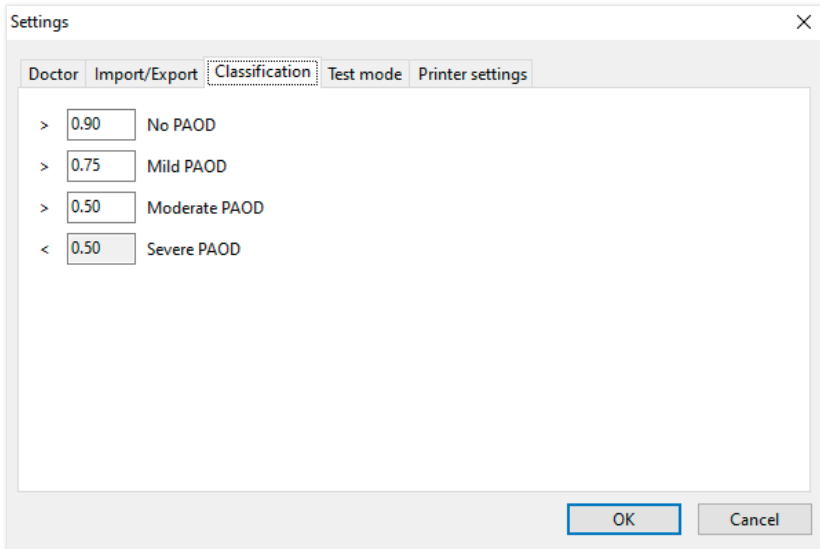
When selecting this option in the practice environment, it is particularly important to ensure that the active patient in the practice EDP is identical to the exported patient.

With the active option "Create PDF file parallel to GDT export" a PDF file is created with the GDT export.

In order to be able to display special characters from certain foreign languages in the GDT, the UTF-8 character set must be used. This does not correspond to the GDT standard and must be specifically selected using the “Use UTF-8 character set” option.

3.4.3 “Assessment” subtab

Fig. 20



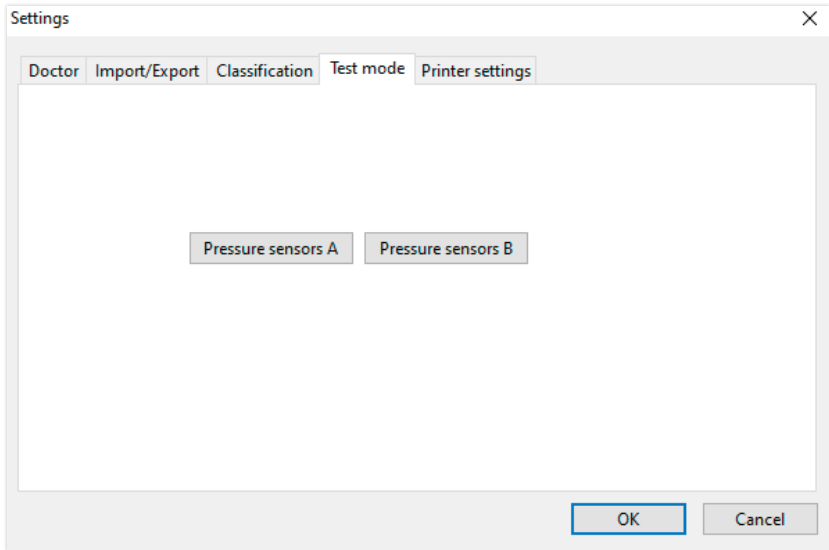
Adjustment of the limits for grading the ABI value.



Changes only take effect after restarting the program.

3.4.4 “Test mode” subtab

Fig. 21



The test mode is activated via the “Pressure sensors A” button or “Pressure sensors B”. The test mode is ended again via the “End test” button.

This function is required, for example, for the pressure test as part of metrological controls.

(optional)

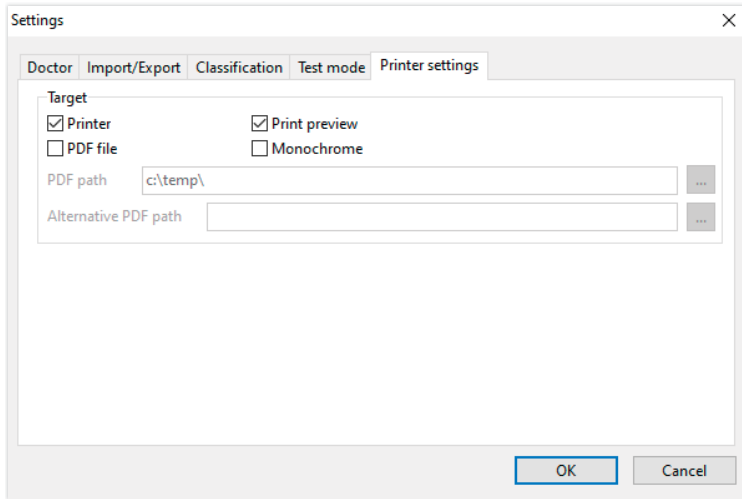
The functional test of the device with the “PWV” option requires special simulators and must be carried out by the manufacturer.



“Pressure sensors B” can only be activated from serial number 466 20000.

3.4.5 “Print settings” subtab

Fig. 22



In the “Print settings” tab, you specify whether the printout is to be output in paper form, as a screen printout and/or as a PDF document after the respective [Print...] buttons have been pressed in the program sequence.

If “Printer” is selected, the Windows print dialogue is displayed when the [Print...] button is pressed in the program flow.

If “Print preview” is also selected, the print preview is displayed before printing.

If “PDF file” is selected, a PDF file will be created. The file name of this PDF file is application-specific and is described in more detail in the individual applications.



At least one medium “Printer” or “PDF file” must be selected.

If the option “Monochrome” is selected, the printout will be monochrome.

3.4.6 Error codes

(82) Measurement error/no measured value displayed -> Repeat measurement

If no measurement result is displayed for the blood pressure, check the cuff and hoses, then carry out a repeat measurement. If no measurement result is repeatedly displayed, this can indicate a circulatory disorder or media sclerosis. Further investigations are recommended here.

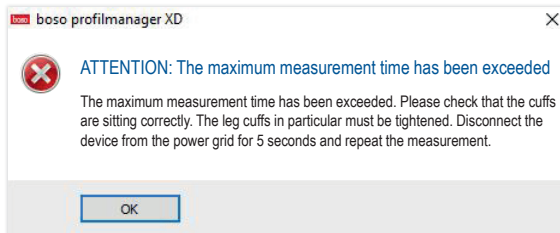
(83) Connect cuff

(89) System error -> Device should be checked by the manufacturer's service department



Danger: Maximum measurement time has been exceeded.

Fig. 23



This message is triggered by too long a measurement duration, which may not exceed 150 seconds.

A cuff that is applied incorrectly and/or too loosely can increase the measurement time and/or lead to re-pumping.

It is also important to ensure that the cuff does not lie directly on the bed. This can cause the cuffs to slip jerkily on the bed, which in turn leads to re-pumping. A protective pad made of paper can help here.

Unplug the device for 5 seconds to resolve the issue. If the problem occurs again immediately after starting a new measurement, please send the device to the manufacturer for examination.

4 “24h measurement” application

4.1 “Patient” tab

See section “2.1 Patient tab - valid for all applications”.
 “Settings” button see chapter 4.7.

4.2 “Measurement data” tab

The screenshot shows the 'bosoprof-manager-KD' software interface. At the top, there is a navigation bar with tabs: Patient, Measurements, Sys/Dia profile, MAP profile, PP profile, and Statistics. The 'Patient' tab is active, showing a patient profile for 'bosoprof-manager-KD'. A central window displays a table of measurement data for a selected patient. The table has columns for Date, SYS, DIA, PUL, MAP, PP, Ave., Exclude, I, S, °C, SpO2, O2sat, GSA, CNP, cGKc1, and Remark. A right-hand panel shows a summary of the selected period (6/8/2021 - 6/9/2021) and device (TM-2450 B). A bottom panel contains a list of actions such as 'Delete period...', 'Remarks...', 'Export GDT', 'Manual entries...', 'Print...', 'Programme...', and 'Read out measurements...'.

Fig. 24

All measurements that have been read in for the selected patient are displayed here (see Fig. 24).

The 24h measuring device is initialised here and data is read from the device.

To switch to this tab, a patient must be selected. The program starts patient-neutral. A help mask appears without a manually selected patient or a patient imported automatically via the GDT interface.

The blood pressure monitor with which the series of measurements was carried out is displayed next to the time period.

Choose the desired period.

see Fig. 24

Period	Device	LC
6/8/2021 - 6/9/2021	TM-2450 B	1
3/10/2011 - 3/11/2011	TM-2430	
4/15/2008 - 4/16/2008	TM-2430	

Description "LC": License code 1

Patient	Measurements	Sys/Dia profile				MAP profile		PP profile			Statistics				Remark		
Date	SYS	DIA	PUL	MAP	PP	Arr.	Exclude	S	°C	hPa	Osc.	cSYS	cDIA	cMAP	cExc1	Remark	
1 Tue, 6/8/2021 - 9:45 AM	112	77	81	89	35		<input type="checkbox"/>		25.4	953		113	75	90	<input type="checkbox"/>		
2 Tue, 6/8/2021 - 10:00 AM	112	79	81	90	33		<input type="checkbox"/>		24.9	954		114	75	90	<input type="checkbox"/>		
3 Tue, 6/8/2021 - 10:15 AM	111	79	83	90	32		<input type="checkbox"/>		24.7	953		114	75	90	<input type="checkbox"/>		
4 Tue, 6/8/2021 - 10:30 AM	112	78	81	89	34		<input type="checkbox"/>		24.7	954		113	75	90	<input type="checkbox"/>		
5 Tue, 6/8/2021 - 10:45 AM	113	78	81	90	35		<input type="checkbox"/>		24.6	953		113	75	90	<input type="checkbox"/>		
6 Tue, 6/8/2021 - 11:00 AM	111	79	81	90	32		<input type="checkbox"/>		24.7	954		114	75	90	<input type="checkbox"/>		
7 Tue, 6/8/2021 - 11:15 AM	113	79	81	90	34		<input type="checkbox"/>		24.7	953		113	75	90	<input type="checkbox"/>		
▲ 1	▲ 2	▲ 3	▲ 4	▲ 5	▲ 6	▲ 7	▲ 8	▲ 9	▲ 10	▲ 11	▲ 12	▲ 13	▲ 14	▲ 15	▲ 16	▲ 17	▲ 18

The columns have the following content:

- 1: Consecutive numbering of the measurements
- 2: Date and time of the measurement
- 3: SYS = Systolic blood pressure value (peripheral)
- 4: DIA = Diastolic blood pressure value (peripheral)
- 5: PUL = Heart rate
- 6: MAP = Mean arterial blood pressure value, calculated from DIA + 1/3 pulse pressure (peripheral)
- 7: PP = Pulse pressure (SYS – DIA)
- 8: Arrhythmia
- 9: Exclude = Mark removes the measurement from the evaluation in profile and statistics
- 10: S = Measurement during the night phase

Value display for TM-2450

- 11: Temperature in °C
- 12: Relative air pressure in hPa
- 13: Pulse curve

Value display for license code 1

- 14: cSYS = Systolic blood pressure value (central)
- 15: cDIA = Diastolic blood pressure value (central)
- 16: cMAP = Mean arterial blood pressure value (central)
- 17: cExclude = Removes central blood pressure values from the evaluation

- 18: Remark: To add a remark to a measurement, double-click in the line of the measurement. The input field is opened. If the upper arm circumference is recorded in the patient data, the appropriate cuff size is displayed.

4.2.1 Pressure curve/cBP (TM-2450)


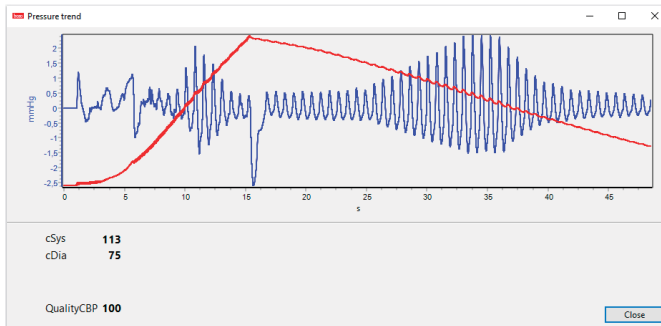
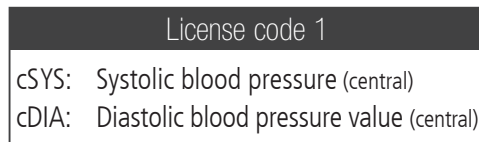
Click on “” to open the display of the pressure curve (see Fig. 26). With the license code 1 further parameters are displayed.

Fig. 26



Optional:



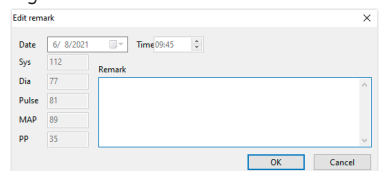
4.2.2 “Delete period...” button (see Fig. 24)

Irrevocable deletion of a complete series of measurements.

4.2.3 “Remarks...” button

Remark on a complete series of measurements (see Fig. 24).

Fig. 27



4.2.4 “Export GDT” button

Manual generation of the GDT export file. Only available with previous GDT import of the active patient (see Fig. 24)

4.2.5 “Manual entries...” button

Additional measured values can be added to the active series of measurements, edited or deleted here (see Fig. 24)

4.2.6 “Print...” button

Printout of the measured value list. If “PDF file” was selected in the print settings (chapter 4.7.3), a PDF file is created. The file name of this PDF file is tm_pat#_YYYYMMDD_m.pdf (see Fig. 24).

pat# = Patient number
YYYYMMDD = Date of measurement
m = Identification letter for measurement

4.2.7 “Program ...” button (see Fig. 24)

Fig. 28

TM-2450 settings

Patient **Mustermann, Manfred**

Mode

Standard periods/intervals

Sleep button

Programmable periods/intervals

Date/Time

Current system time 11/10/2022 12:24 AM

TM-2450 time 11/10/2022 9:25 AM

Intervals

	Day	Night
Start time	7 :00	22 :00
Interval	15	30

Actions

Apply system time

Show measurement

Licence code 0

Recommended cuff size

M

Miscellaneous

Max. infl. press. 200 mmHg

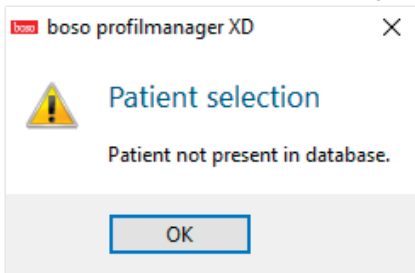
OK Cancel

The 24h measuring device can be programmed with a unique, max. 10-digit patient number. This procedure offers the advantage that when the measurement data is read out, it can be assigned directly to the correct patient.



The 24h measuring device must be programmed before it is applied to a patient. Otherwise you will get the following error message when reading out the measured values:

Fig. 29



You must confirm this error message with "OK" and select the correct patient in the newly displayed patient list.

The current patient is automatically taken over in the programming window and the patient number assigned to the device (software-side generation of a numeric identifier, so alphanumeric patient numbers can also be managed in the bosco profil-manager XD).

You can define a maximum inflation pressure in the "Maximum pressure" field. The inflation height of the blood pressure monitor is limited by the value entered here.



If the patient's systolic blood pressure value is similar to or above this value, no blood pressure measurement can be taken. The device then returns an error message.





TM-2430 devices with serial number < SN M 0713550 do not have the option of programmable patient number and maximum pressure.

Three different modes can be programmed

Default Periods/Intervals

If this mode is selected, the device measures every 15 minutes from 07:00 to 22:00 and every 30 minutes from 22:00 to 07:00.

Sleep button

In this mode, the patient has the option of pressing the AUTO button   to determine on the 24h measuring device when the night or day interval should begin. This programming offers the advantage that the measurement intervals can be individually adjusted to the patient. For example, in patients with irregular sleep patterns. The interval duration is 15 minutes in the day interval and 30 minutes in the night interval.

Programmable periods/intervals

In this mode, two freely selectable intervals and periods can be programmed. The interval duration is individually adjustable (5/10/15/20/30/60/120 minutes).

Show measured value

By activating or deactivating, you can select here whether the measured value should be displayed after the measurement or not.

Take over PC time

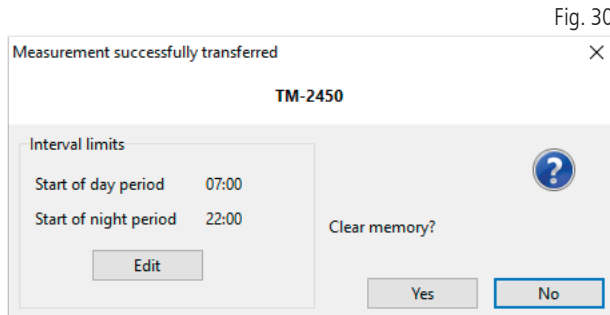
By activating, the date and time settings set on your PC are applied.

4.2.8 “Read measured values ...” button

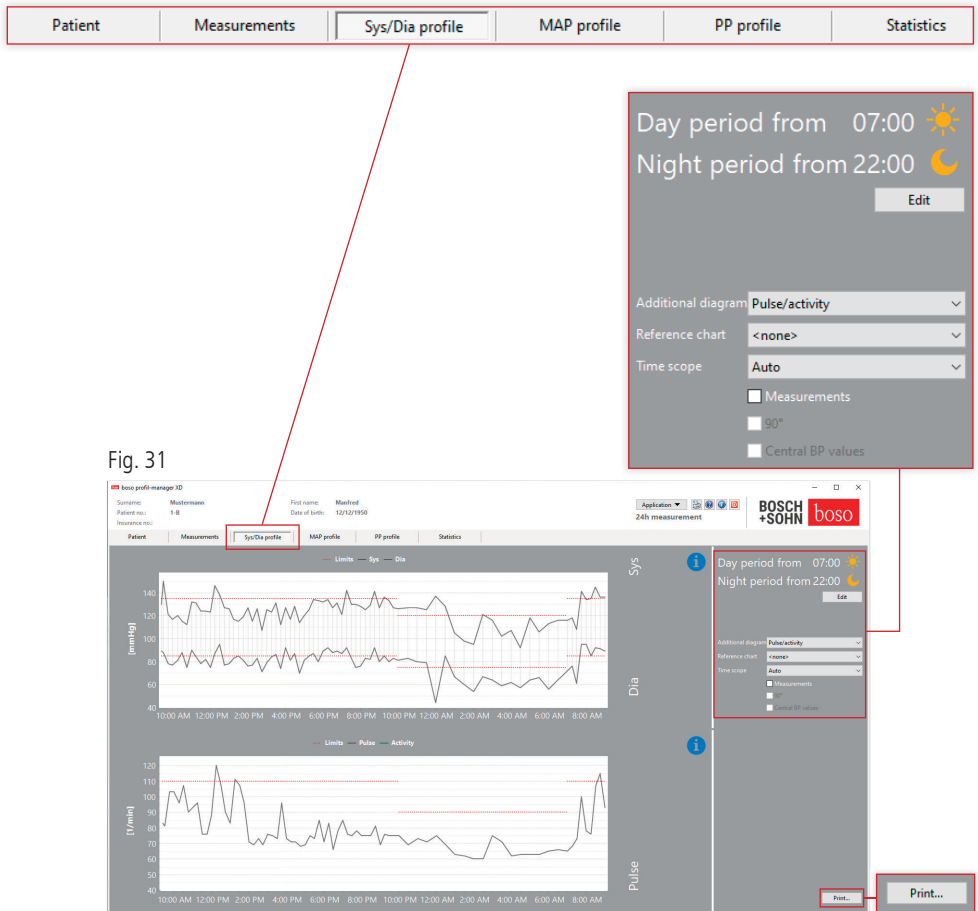
Connect the measuring device to the PC connection cable before pressing the “Read measured values” button. The measurement data is then transferred from the connected measuring device.

After the data transfer, the interval limits can be individually adjusted to the patient’s actual daily routine using the “Change” button.

The measured value memory of the device should be deleted by pressing the “Yes” button.



4.3 “Profile Sys/Dia” tab



The blood pressure course is displayed here.

To get more detailed information on individual measured values, move the mouse pointer to the measurement. The date, the time and the measured value are displayed at the top left of the diagram.

A zoom function is available to display areas of the curve in more detail. With the left mouse button pressed, the zoom area is selected by moving the mouse from bottom left to top right within the diagram. The zoom function is cancelled by moving the mouse within the diagram from top right to bottom left while holding down the left mouse button.

4.3.1 Central blood pressure values (TM-2450)

“Central blood pressure values” checkbox: additional central blood pressure values (active with license code 1).

4.3.2 “Change” button

The interval limits can be individually adapted to the patient’s actual daily routine using the “Change” button.

4.3.3 “Comparison curve” selection field

Here the data of an additional 24h measurement can be read into the current graphic and the course of both series of measurements can be compared directly (see Fig. 31).

4.3.4 “Time window” selection field

Selection of the time range over which the measurements are displayed. You can choose between Auto and Tag. The “Auto” setting is selected by default. The time window is scaled from the first to the last measurement.

Exactly 24 hours are displayed with the “Day” setting.

By pressing the right mouse button in the diagram, the graphic can be moved horizontally with the mouse (see Fig. 31).

4.3.5 “Print...” button

Printout of the SYS/DIA profile and the pulse profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 4.7.3), a PDF file is created. The file name of this PDF file is tm_pat#_YYYYMMDD_sys.pdf (see Fig. 31).

pat# = Patient number
YYYYMMDD = Date of measurement
sys = Identification letter for SYS/DIA

4.4 “Profile MAP” tab

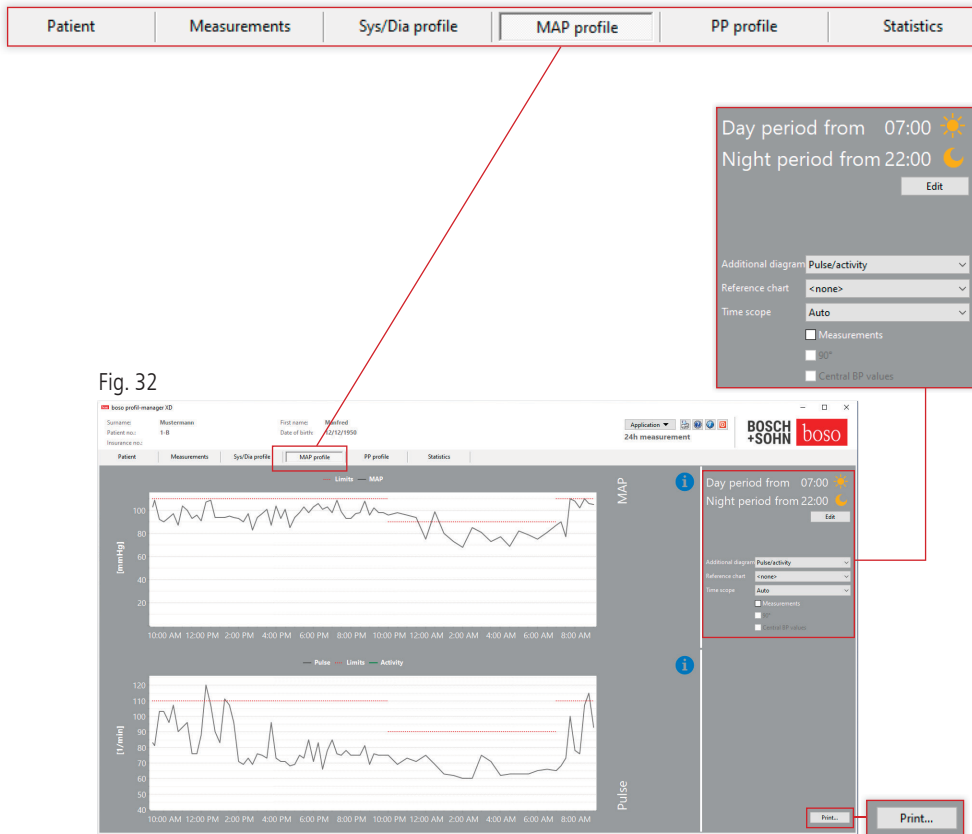


Fig. 32

The course of the calculated mean arterial blood pressure is displayed here ($\text{MAP} = \text{diastolic DIA} + 1/3 \text{ pulse pressure PP}$).

To get more detailed information on individual measured values, move the mouse pointer to the measurement. The date, the time and the measured value are displayed at the top left of the diagram. A zoom function is available to display areas of the curve in more detail. With the left mouse button pressed, the zoom area is selected by moving the mouse from bottom left to top right within the diagram. The zoom function is cancelled by moving the mouse within the diagram from top right to bottom left while holding down the left mouse button.

4.4.1 Central blood pressure values (TM-2450)

“Central blood pressure values” checkbox: additional central blood pressure values (active with license code 1).

4.4.2 “Change” button

The interval limits can be individually adapted to the patient’s actual daily routine using the “Change” button.

4.4.3 “Comparison curve” selection field

Here the data of an additional 24h measurement can be read into the current graphic and the course of both series of measurements can be compared directly (see Fig. 32).

4.4.4 “Time window” selection field

Selection of the time range over which the measurements are displayed. You can choose between Auto and Tag. The “Auto” setting is selected by default. The time window is scaled from the first to the last measurement.

Exactly 24 hours are displayed with the “Day” setting.

By pressing the right mouse button in the diagram, the graphic can be moved horizontally with the mouse (see Fig. 32).

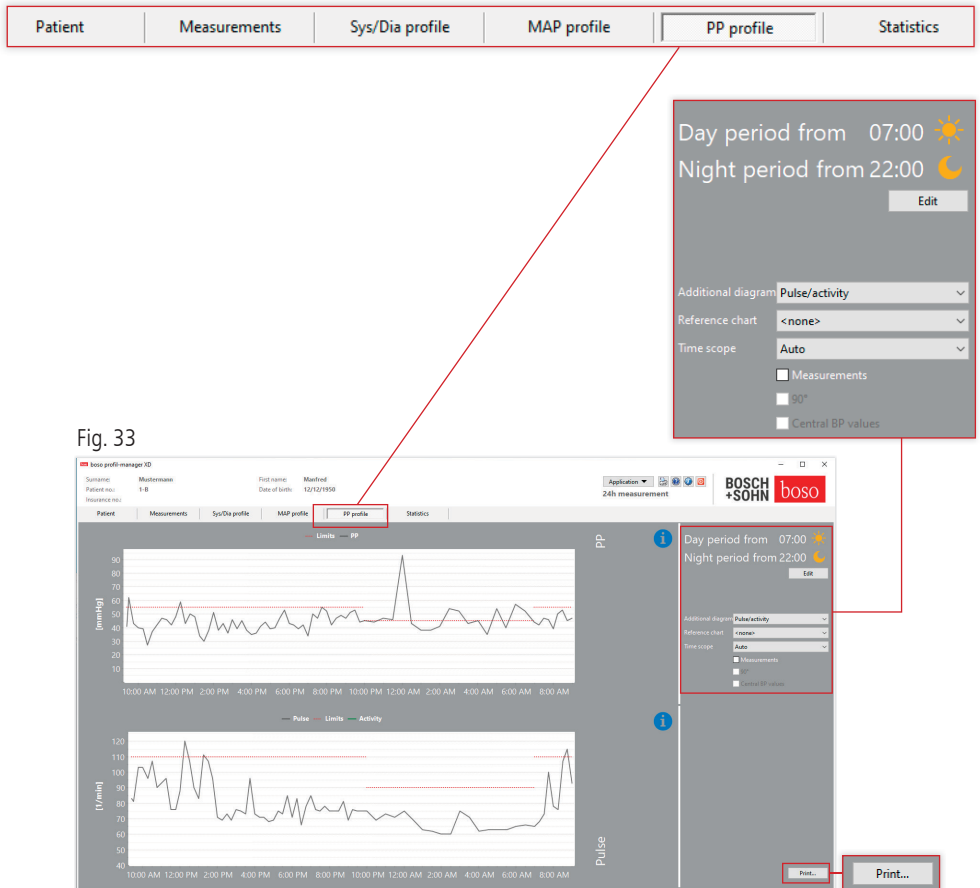
4.4.5 “Print...” button

Printout of the MAP profile and the heart rate profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 4.7.3), a PDF file is created. The file name of this PDF file is tm_pat#_YYYYMMDD_map.pdf (see Fig. 32).

pat# = Patient number
YYYYMMDD = Date of measurement
map = Code letter for MAP

4.5 “Profile PP” tab



The course of the calculated pulse pressure is displayed here ($PP = SYS - DIA$). To get more detailed information on individual measured values, move the mouse pointer to the measurement. The date, the time and the measured value are displayed at the top left of the diagram. A zoom function is available to display areas of the curve in more detail. With the left mouse button pressed, the zoom area is selected by moving the mouse from bottom left to top right within the diagram. The zoom function is cancelled by moving the mouse within the diagram from top right to bottom left while holding down the left mouse button.

4.5.1 Central blood pressure values (TM-2450)

“Central blood pressure values” checkbox: additional central blood pressure values (active with license code 1).

4.5.2 “Change” button

The interval limits can be individually adapted to the patient’s actual daily routine using the “Change” button.

4.5.3 “Comparison curve” selection field

Here the data of an additional 24h measurement can be read into the current graphic and the course of both series of measurements can be compared directly.

4.5.4 “Time window” selection field

Selection of the time range over which the measurements are displayed. You can choose between Auto and Tag. The “Auto” setting is selected by default. The time window is scaled from the first to the last measurement.

Exactly 24 hours are displayed with the “Day” setting.

By pressing the right mouse button in the diagram, the graphic can be moved horizontally with the mouse (see Fig. 33).

4.5.5 “Print...” button

Printout of the pulse pressure profile and the pulse profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 4.7.3), a PDF file is created. The file name of this PDF file is tm_pat#_YYYYMMDD_pp.pdf.

pat# = Patient number
YYYYMMDD = Date of measurement
pp = Code letter for pulse pressure (see Fig. 33)

4.6 “Statistics” tab

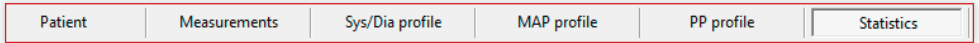
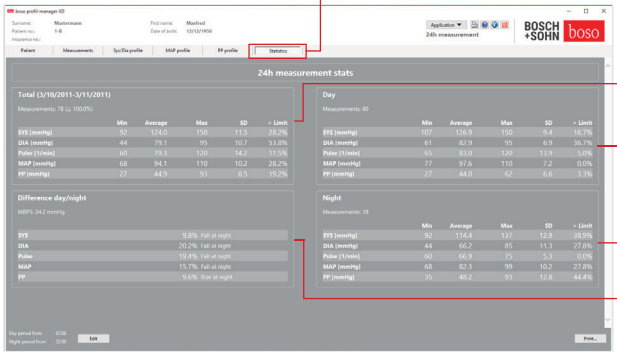


Fig. 34



The measurements of the total, day and night period are evaluated separately. The total of the readings is displayed in each time period. With license code 1 and activated central blood pressure values, the central blood pressure values are shown in brackets. The following values are output in the individual columns:

- Min:** Smallest value in the corresponding interval
- Mean:** Arithmetic mean in the corresponding interval
- Max:** Largest value in the corresponding interval
- StdDev:** Standard deviation in the corresponding interval
- > Limit:** Percentage part above the specified limits
- MBPS:** Morning blood pressure surge
The MBPS is an indicator of the rise in blood pressure after waking up. $MBPS = MwSysDay - MwSysNight$
- Mean day =** Mean of the systolic values from the first two hours of the day interval
- Mean night =** Mean of the 3 systolic values around the lowest systolic value in the night interval (one value before the lowest value, the lowest value itself and one value after the lowest value). Percentage rise/fall at night is displayed.

Total (3/10/2011-3/11/2011)

Measurements: 78 (\pm 100.0%)

	Min	Average	Max	SD	> Limit
SYS [mmHg]	92	124.0	150	11.5	28.2%
DIA [mmHg]	44	79.1	95	10.7	53.8%
Pulse [1/min]	60	79.3	120	14.2	11.5%
MAP [mmHg]	68	94.1	110	10.2	28.2%
PP [mmHg]	27	44.9	93	8.5	19.2%

Day

Measurements: 60

	Min	Average	Max	SD	> Limit
SYS [mmHg]	107	126.9	150	9.4	16.7%
DIA [mmHg]	61	82.9	95	6.9	36.7%
Pulse [1/min]	65	83.0	120	13.9	5.0%
MAP [mmHg]	77	97.6	110	7.2	0.0%
PP [mmHg]	27	44.0	62	6.6	3.3%

Night

Measurements: 18

	Min	Average	Max	SD	> Limit
SYS [mmHg]	92	114.4	137	12.9	38.9%
DIA [mmHg]	44	66.2	85	11.3	27.8%
Pulse [1/min]	60	66.9	75	5.3	0.0%
MAP [mmHg]	68	82.3	99	10.2	27.8%
PP [mmHg]	35	48.2	93	12.8	44.4%

Difference day/night

MBPS: 24.2 mmHg

SYS	9.8%	Fall at night
DIA	20.2%	Fall at night
Pulse	19.4%	Fall at night
MAP	15.7%	Fall at night
PP	9.6%	Rise at night

4.6.1 Display central statistics (TM-2450)

Select the Statistics tab and activate the “Central blood pressure values” checkbox with profile SYS/DIA, MAP, PP (see Fig. 34).

4.6.2 “Change” button

The interval limits can be individually adapted to the patient’s actual daily routine using the “Change” button (see Fig. 34).

4.6.3 “Print...” button

Printout of the SYS/DIA profile and the pulse profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 4.7.3), a PDF file is created. The file name of this PDF file is tm_pat#_YYYYMMDD_sys.pdf (see Fig. 34).

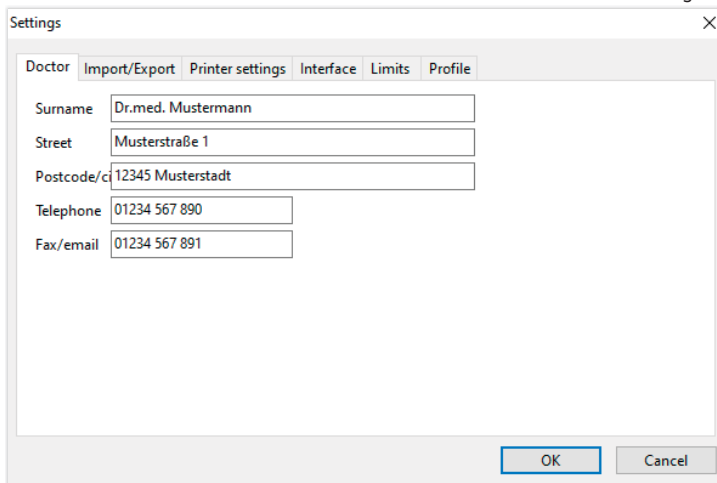
pat# = Patient number
YYYYMMDD = Date of measurement
sys = Identification letter for SYS/DIA

4.7 Button

“Settings...” in the “Patient” tab

4.7.1 “Physician” subtab

Fig. 35



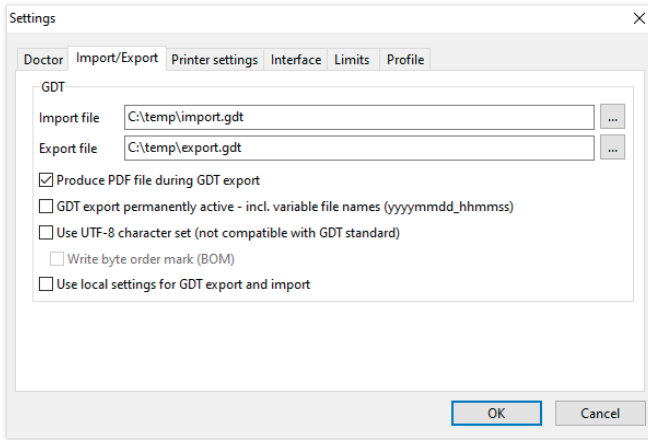
The screenshot shows a window titled "Settings" with a close button (X) in the top right corner. The window has several tabs: "Doctor", "Import/Export", "Printer settings", "Interface", "Limits", and "Profile". The "Doctor" tab is currently selected. Below the tabs, there are five text input fields with labels to their left:

- Surname: Dr.med. Mustermann
- Street: Musterstraße 1
- Postcode/city: 12345 Musterstadt
- Telephone: 01234 567 890
- Fax/email: 01234 567 891

At the bottom right of the dialog, there are two buttons: "OK" and "Cancel".

4.7.2 “Import/Export” subtab

Fig. 36



When using a practice EDP that supports the GDT interface, the path and file names for the export or import file are specified here. The buttons next to the input fields for import and export files give you access to the Windows directory structure.

Example: c:\prax_edv\import.gdt

Import file = Export file of the practice EDP

Export file = Import file of the practice EDP

The GDT import takes place automatically when the program starts or manually by confirming the “Export/Import -> Import GDT” button if there is a valid GDT import file in the specified directory.

The GDT export only takes place if the patient imported from the practice EDP is active. The export takes place automatically when the program is exited (provided measurement data was read in from the device during the current program session) or manually at any time by clicking on the “Export GDT” button in the “Measurement data” tab.

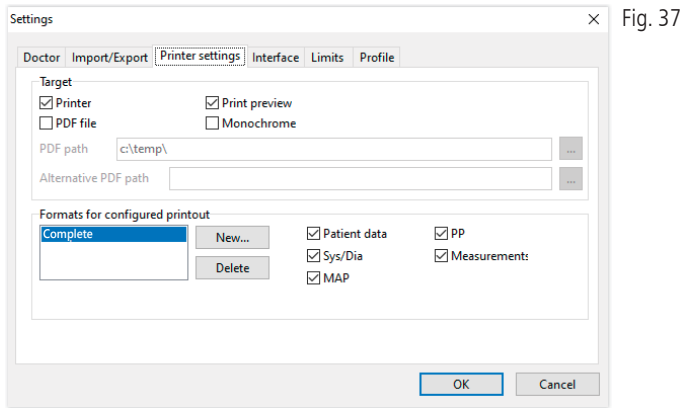


The data export is deactivated if the patient has changed after the automatic import. It will be reactivated when that patient is re-selected. The data export is also deactivated if no import has previously taken place.

For more information on the available options “Create PDF file parallel to GDT export”, “GDT export permanently active” and “Use UTF-8 character set” see 3.4.2.

4.7.3 “Print settings” subtab

If the “Central blood pressure values” checkbox is active, the central blood pressure values and statistics are printed.



In the “Physician” subtab, the personal data of the attending physician is entered as the basis for the footer in the printout.

In the “Print settings” tab, you specify whether the printout is to be output in paper form, as a screen printout and/or as a PDF document after the respective [Print...] buttons have been pressed in the program sequence.

If “Printer” is selected, the Windows print dialogue is displayed when the [Print...] button is pressed in the program flow.

If “Print preview” is also selected, the print preview is displayed before printing.

If “PDF file” is selected, a PDF file will be created. The file name of this PDF file is application-specific and is described in more detail in the individual applications.



At least one medium “Printer” or “PDF file” must be selected.

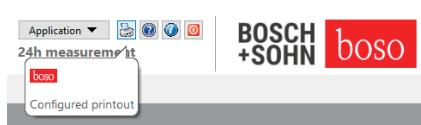
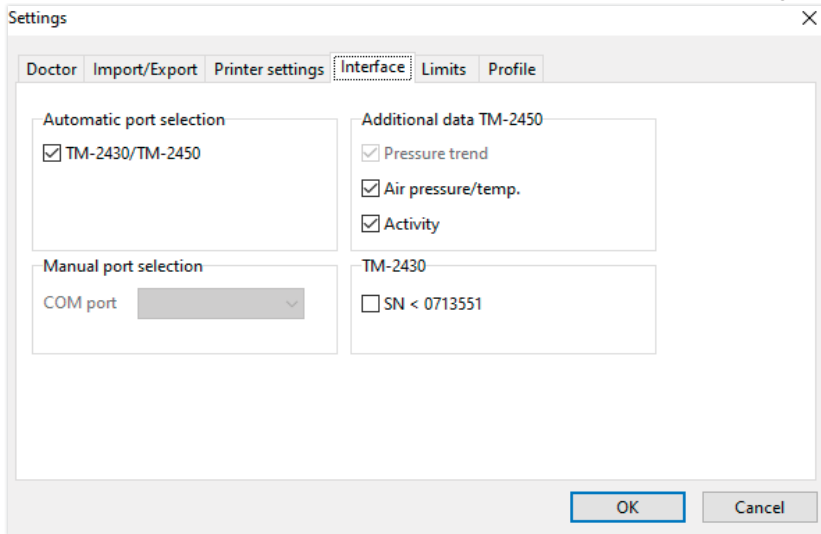


Fig. 38

If the option “Monochrome” is selected, the printout will be monochrome. By clicking on the “Configured printout” printer icon, the printout format configured here is used and only the pages selected here are printed.

4.7.4 “Interface” subtab

Fig. 39



Specify here how the connection between the 24h measuring device and the PC is established.

If the “Automatic USB selection” option is active, the software checks which USB port a 24-hour measuring device is connected to before each data transfer. If several devices are connected at the same time, please remove all devices except the one to be used. A corresponding warning reminds you of this.

If the “Automatic USB selection” option is not active, the serial (COM) or USB port selected in the port list is used for data transfer.

Devices of older designs use a reduced command set (without programmable patient number and maximum pressure). For TM-2430 devices with a serial number < SN M0713551, the corresponding option must be selected.

4.7.5 “Limits” subtab

Fig. 40

The screenshot shows the 'Limits' subtab in a 'Settings' window. The window has a title bar with 'Settings' and a close button. Below the title bar are several tabs: 'Doctor', 'Import/Export', 'Printer settings', 'Interface', 'Limits', and 'Profile'. The 'Limits' tab is selected. The main content area is divided into three sections: 'Total', 'Day/night', and 'Central'. Each section contains input fields for various parameters and an 'Activate' checkbox.

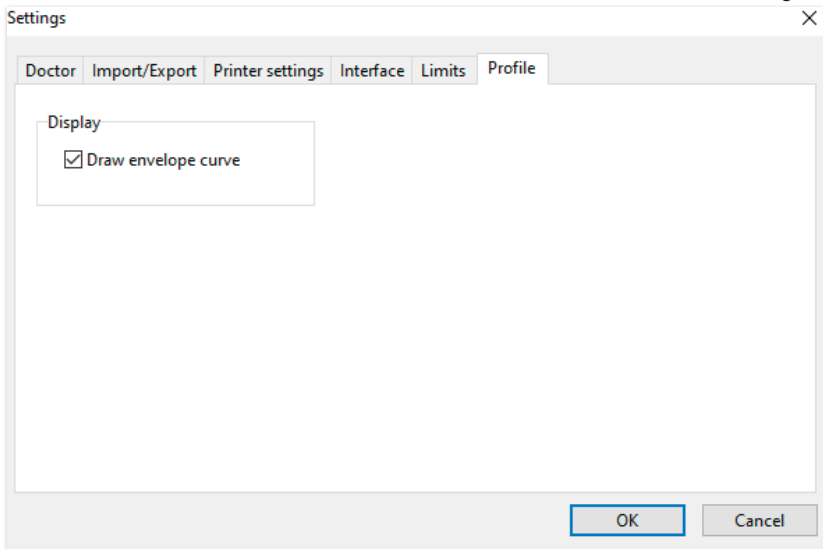
Section	Parameter	Day	Night
Total	SYS	130	-
	DIA	80	-
	Pulse	100	-
	MAP	100	-
	PP	50	-
Day/night	SYS day	135	120
	DIA day	85	75
	Pulse day	110	90
	MAP day	110	90
	PP day	55	45
<input checked="" type="checkbox"/> Activate			
Central	SYS day	135	135
	DIA day	85	85
	MAP day	110	110
<input checked="" type="checkbox"/> Activate			

At the bottom right of the window are 'OK' and 'Cancel' buttons.

In order to enable an individual evaluation, the limit values for the individual periods can be defined. The setting of the limit values for day and night refer to the defined interval times. Central blood pressure limits are disabled by default and must be enabled if required.

4.7.6 “Profile” subtab

Fig. 41



In the profile displays (“Profile Sys/Dia, MAP, PP” tab) an envelope curve (connecting line between the individual measurement points) is drawn by default and the limit values are displayed as horizontal lines.

Both envelope curve and limit lines can be hidden here.

5 “Patient measurement” application

5.1 “Patient” tab

See section “2.1 Patient tab - valid for all applications”.
“Settings” button see chapter 5.7.

5.2 “Measurement data” tab

The screenshot displays the 'Patient measurement' application interface. At the top, there are navigation tabs: Patient, Measurements (selected), Sys/Dia profile, MAP profile, PP profile, and Statistics. Below the tabs, there are two panels: 'Period' (4/6/2013 - 6/27/2013) and 'Device' (medlife PCS). The main area shows a table of measurements with columns for Date, Weight, SYS, DIA, PUL, MAP, PP/Ar, Exclude, and Remark. The table contains 28 rows of data. Below the table, there are filter options: All (selected), Morning, Afternoon, and Period (1/1/2022 - 12/31/2022). On the right side, there is a 'Bosch+SOHN' logo and a 'Delete period...' dialog box with buttons for 'Export GDT', 'Manual measurements...', 'Print...', 'Read out measurements...', and 'Interval limits...'.

Fig. 42

Date	Weight	SYS	DIA	PUL	MAP	PP/Ar	Exclude	Remark
27-Jan-4/7/2013 - 4:10 AM	150	94	65	211	71			
3-Feb-4/7/2013 - 4:37 AM	150	92	67	211	61			
4-Feb-4/7/2013 - 4:44 AM	148	74	70	204	68			
5-Feb-4/7/2013 - 4:49 AM	152	87	69	219	68			
6-Feb-4/7/2013 - 4:54 AM	176	87	67	217	69			
7-Feb-4/7/2013 - 4:59 AM	150	99	67	219	61			
8-Feb-4/7/2013 - 4:58 AM	146	91	69	202	66			
9-Feb-4/7/2013 - 4:59 AM	153	92	64	216	71			
10-Feb-4/7/2013 - 4:54 AM	146	74	65	213	64			
11-Feb-4/7/2013 - 4:53 AM	140	84	68	219	74			
12-Feb-4/7/2013 - 4:52 AM	161	89	65	209	68			
13-Feb-4/7/2013 - 4:54 AM	153	81	64	216	71			
14-Feb-4/7/2013 - 4:59 AM	162	91	69	219	71			
15-Feb-4/7/2013 - 4:44 AM	177	86	63	216	61			
16-Feb-4/7/2013 - 4:52 AM	161	89	63	213	72			
17-Feb-4/7/2013 - 4:57 AM	149	84	70	211	77			
18-Feb-4/7/2013 - 4:52 AM	174	92	67	219	62			
19-Feb-4/7/2013 - 4:07 AM	146	94	71	219	70			
20-Feb-4/7/2013 - 4:02 AM	148	74	64	214	70			
21-Feb-4/7/2013 - 4:17 AM	148	91	70	219	67			
22-Feb-4/7/2013 - 4:22 AM	150	74	70	207	67			
23-Feb-4/7/2013 - 4:37 AM	154	89	71	211	66			
24-Feb-4/7/2013 - 4:22 AM	150	92	67	217	76			
25-Feb-4/7/2013 - 4:24 AM	179	92	67	211	67			
26-Feb-4/7/2013 - 4:29 AM	152	89	64	214	100			
27-Feb-4/7/2013 - 4:24 AM	144	89	69	214	104			
28-Feb-4/7/2013 - 4:41 AM	142	89	64	214	100			
29-Feb-4/7/2013 - 4:44 AM	141	89	69	214	88			
30-Feb-4/7/2013 - 4:59 AM	156	95	67	214	92			
31-Feb-4/7/2013 - 4:54 AM	146	94	74	219	100			
1-Mar-4/7/2013 - 4:59 AM	140	101	69	214	99			
2-Mar-4/7/2013 - 4:05 AM	171	92	68	211	90			
3-Mar-4/7/2013 - 4:11 AM	149	90	68	211	104			
4-Mar-4/7/2013 - 4:14 AM	148	89	64	211	100			
5-Mar-4/7/2013 - 4:20 AM	149	104	70	219	94			
6-Mar-4/7/2013 - 4:16 AM	146	97	64	211	89			
7-Mar-4/7/2013 - 4:53 AM	150	94	74	214	84			
8-Mar-4/7/2013 - 4:54 AM	159	99	69	213	69			

All previously read blood pressure measurements for the selected patient are displayed under “Blood pressure”. The blood pressure monitor with which the series of measurements was carried out is displayed next to the time period.

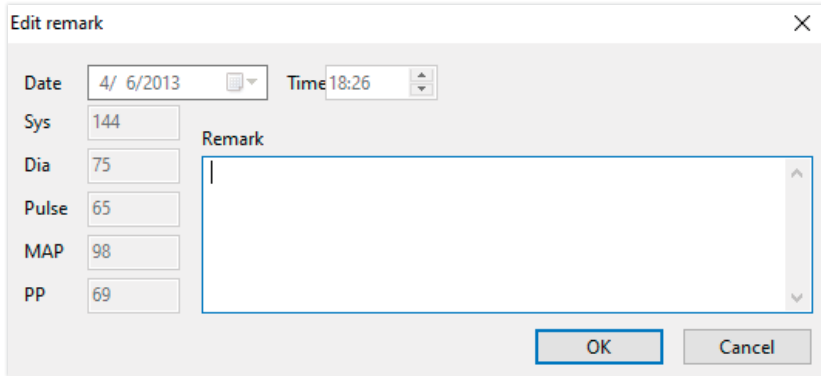
Fig. 43

boso profil-manager XD									
Surname: Smith		First name: John							
Patient no.: 1-B		Date of birth: 12/12/1950							
Insurance no.:									
Patient	Measurements	Sys/Dia profile	MAP profile	PP profile	Statistics				
Blood pressure	Weight								
Date	SYS	DIA	PUL	MAP	PP	Arr.	Exclude	Remark	
1 Sat, 4/6/2013 - 6:26 PM	144	75	65	98	65		<input type="checkbox"/>		
2 Sun, 4/7/2013 - 8:32 AM	159	88	68	112	71		<input type="checkbox"/>		
3 Sun, 4/7/2013 - 6:37 PM	153	92	67	112	61		<input type="checkbox"/>		
4 Mon, 4/8/2013 - 8:44 AM	164	76	72	105	88		<input type="checkbox"/>		
5 Mon, 4/8/2013 - 6:49 PM	152	87	68	109	65		<input type="checkbox"/>		
6 Tue, 4/9/2013 - 8:54 AM	176	87	67	117	89		<input type="checkbox"/>		
7 Tue, 4/9/2013 - 6:59 PM	160	99	67	119	61		<input type="checkbox"/>		

The columns have the following content:

- 1: Consecutive numbering of the measurements
- 2: Date and time of the measurement
- 3: SYS = Systolic blood pressure value
- 4: DIA = Diastolic blood pressure reading
- 5: PUL = Heart rate
- 6: MAP = Mean arterial blood pressure value (from DIA + 1/3 pulse pressure)
- 7: PP = Pulse pressure (SYS – DIA)
- 8: Arr. = Arrhythmia indicator
- 9: Exclude = Mark removes the measurement from the evaluation in profile and statistics
- 10: Remark: To add a remark to a measurement, double-click in the line of the measurement. The input field for remarks opens

Fig. 44



5.2.1 “Delete period ...” button (see Fig. 42)

Irrevocable deletion of a complete series of measurements (see Fig. 42).

5.2.2 “Export GDT” button (see Fig. 42)

Manual generation of the GDT export file. Only available with previous GDT import of the active patient (see Fig. 42).

5.2.3 “Manual readings...” button (see Fig. 42)

Additional measured values can be added to the active measurement series here (see Fig. 42).

5.2.4 “Print...” button (see fig. 42)

Printout of the measured value list.

If “PDF file” was selected in the print settings (chapter 5.7.3), a PDF file is created. The file name of this PDF file is `medi_pat#_YYYYMMDD_m.pdf` (see Fig. 42).

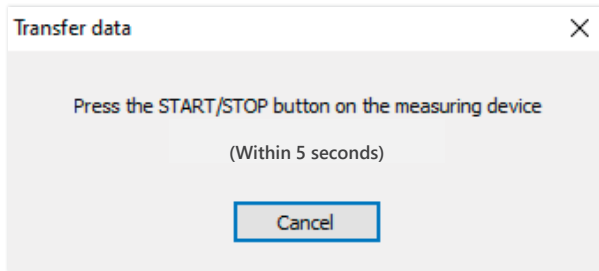
pat# = Patient number
YYYYMMDD = Date of measurement
m = Identification letter for measurement

5.2.5 “Read measured values..” button



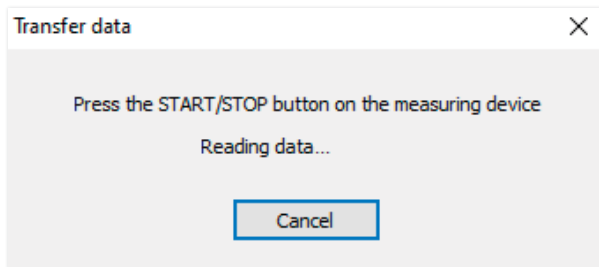
Only for medicus PC2 and medilife PC3.
Connect the measuring device to the PC (see Fig. 42).

Fig. 45



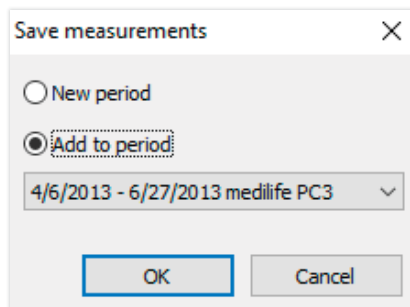
After pressing the “Read out measured values..” button, the START/STOP button on the blood pressure monitor must be pressed within 6 seconds in order to start data transmission on the blood pressure monitor. The measurement data is transmitted from the connected measuring device.

Fig. 46



After successful data transfer, a new period can be created or the data can be appended to an existing period.

Fig. 47



5.2.6 “Interval limits ...” button (see fig. 42)

The limits for morning and afternoon measurements can be defined here. The default is 0:00 to 11:59 in the morning and 12:00 to 23:59 in the afternoon (see Fig. 42).

5.2.7 “All, morning, afternoon” selection (see Fig. 42)

Here the selection of the measured values can be limited to morning measurements or afternoon measurements (see Fig. 42).

5.2.8 “Period” selection (see Fig. 42)

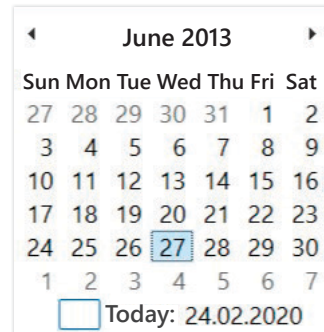
Fig. 48



Fig. 49

By selecting the period, any evaluation period can be selected within all measured values.

A click on the arrow symbol in the date fields opens a calendar sheet for easier selection.



June 2013						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
27	28	29	30	31	1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
1	2	3	4	5	6	7
Today: 24.02.2020						

By clicking on the month or the year, these can be changed directly.

5.3 “Profile Sys/Dia” tab



The blood pressure course is displayed in the upper diagram here.

To get more detailed information on individual measured values, move the mouse pointer to the measurement. The date, time and measured value are displayed at the upper left edge of the diagram. A zoom function is available to display areas of the curve in more detail. With the left mouse button pressed, the zoom area is selected by moving the mouse from bottom left to top right within the diagram. The zoom function is cancelled by moving the mouse within the diagram from top right to bottom left while holding down the left mouse button.

5.3.1 “All, morning, afternoon” selection

Here the selection of the measured values can be limited to morning measurements or afternoon measurements.

5.3.2 “Period” selection (see Fig. 50)

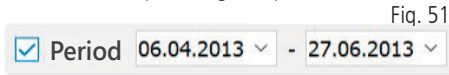
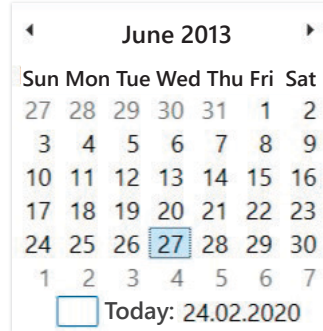


Fig. 52

By selecting the period, any evaluation period can be selected within all measured values.

A click on the arrow symbol in the date fields opens a calendar sheet for easier selection. By clicking on the month or the year, these can be changed directly.



5.3.3 “Time window” selection field (see Fig. 50)

Selection of the time range over which the measurements are displayed. The choices are Auto, Day, Week, Month, Quarter, Year.

The “Auto” setting is selected by default. The time window is scaled from the first to the last measurement.

By pressing the right mouse button in the diagram, the graphic can be moved horizontally with the mouse (see Fig. 50).

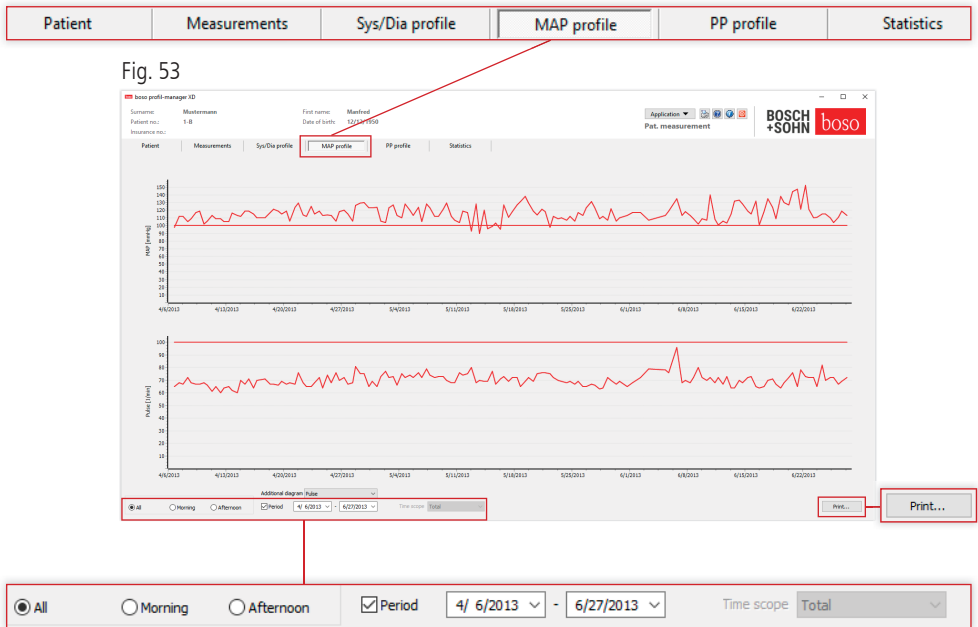
5.3.4 “Print...” button (see Fig. 50)

Printout of the SYS/DIA profile and the pulse profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 5.7.3), a PDF file is created. The file name of this PDF file is `medi_pat#_YYYYMMDD_sys.pdf` (see Fig. 50).

pat# = Patient number
YYYYMMDD = Date of measurement
sys = Identification letter for SYS/DIA

5.4 “Profile MAP” tab



Here, the course of the calculated mean arterial blood pressure is displayed in the upper diagram ($MAP = \text{diastole DIA} + 1/3 \text{ pulse pressure PP}$).

To get more detailed information on individual measured values, move the mouse pointer to the measurement. The date, the time and the measured value are displayed at the top left of the diagram.

A zoom function is available to display areas of the curve in more detail. With the left mouse button pressed, the zoom area is selected by moving the mouse from bottom left to top right within the diagram. The zoom function is cancelled by moving the mouse within the diagram from top right to bottom left while holding down the left mouse button.

5.4.1 “All, morning, afternoon” selection

Here the selection of the measured values can be limited to morning measurements or afternoon measurements.

5.4.2 “Period” selection (see Fig. 53)

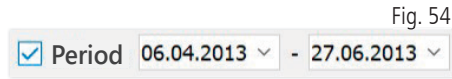
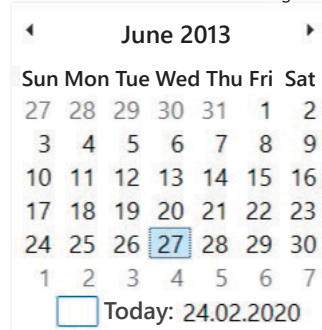


Fig. 55

By selecting the period, any evaluation period can be selected within all measured values.

A click on the arrow symbol in the date fields opens a calendar sheet for easier selection. By clicking on the month or the year, these can be changed directly.



5.4.3 “Time window” selection field (see Fig. 50)

Selection of the time range over which the measurements are displayed. The choices are Auto, Day, Week, Month, Quarter, Year.

The “Auto” setting is selected by default. The time window is scaled from the first to the last measurement.

By pressing the right mouse button in the diagram, the graphic can be moved horizontally with the mouse.

5.4.4 “Print...” button (see Fig. 50)

Printout of the MAP profile and the heart rate profile as well as the statistics.

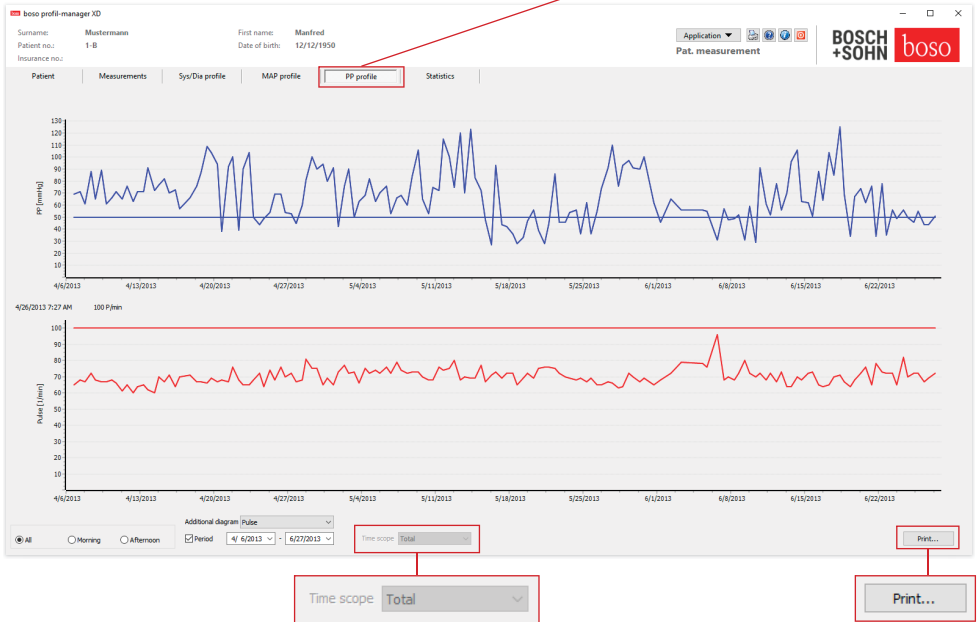
If “PDF file” was selected in the print settings (chapter 5.7.3), a PDF file is created. The file name of this PDF file is medi_pat#_YYYYMMDD_map.pdf

pat# = Patient number
YYYYMMDD = Date of measurement
map = Code letter for MAP

5.5 “Profile PP” tab



Fig. 56



The course of the calculated pulse pressure is displayed in the upper diagram (PP = SYS – DIA).

To get more detailed information on individual measured values, move the mouse pointer to the measurement. The date, the time and the measured value are displayed at the top left of the diagram.

A zoom function is available to display areas of the curve in more detail. With the left mouse button pressed, the zoom area is selected by moving the mouse from bottom left to top right within the diagram. The zoom function is cancelled by moving the mouse within the diagram from top right to bottom left while holding down the left mouse button.

5.5.1 “All, morning, afternoon” selection

Here the selection of the measured values can be limited to morning measurements or afternoon measurements.

5.5.2 “Period” selection (see Fig. 56)

Fig. 57

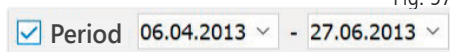
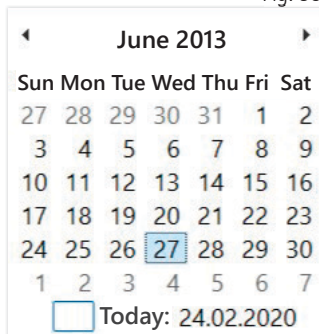


Fig. 58

By selecting the period, any evaluation period can be selected within all measured values.

A click on the arrow symbol in the date fields opens a calendar sheet for easier selection. By clicking on the month or the year, these can be changed directly.



5.5.3 “Time window” selection field (see Fig. 56)

Selection of the time range over which the measurements are displayed. The choices are Auto, Day, Week, Month, Quarter, Year.

The “Auto” setting is selected by default. The time window is scaled from the first to the last measurement.

By pressing the right mouse button in the diagram, the graphic can be moved horizontally with the mouse.

5.5.4 “Print...” button (see Fig. 56)

Printout of the pulse pressure profile and the pulse profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 5.7.3), a PDF file is created. The file name of this PDF file is `medi_pat#_YYYYMMDD_pp.pdf`.

pat# = Patient number
YYYYMMDD = Date of measurement
pp = Code for pulse pressure

5.6 "Statistics" tab



Fig. 59

bosoprofil-manager XD

Surname: Mustermann First name: Manfred
 Patient no.: 1-B Date of birth: 12/12/1950

Application: Pat. measurement BOSCH+SOHN bosoprofil

Patient Measurements Sys/Dia profile MAP profile PP profile **Statistics**

Blood pressure Weight

Pat. measurement statistics (4/6/2013-6/27/2013)

Total (00:00-24:00)
 Measurements: 156 - Arrhythmias detected: 1

	Min	Average	Max	SD	> Limit
SYS [mmHg]	113	160.9	208	19.5	96.2%
DIA [mmHg]	67	93.5	127	11.6	77.6%
Pulse [1/min]	60	70.1	96	4.8	0.0%
HAP [mmHg]	90	116.0	152	10.5	95.5%
PP [mmHg]	27	67.5	125	21.8	76.3%

Morning (00:00-12:00)
 Measurements: 78 - Arrhythmias detected: 1

	Min	Average	Max	SD	> Limit
SYS [mmHg]	113	162.3	208	20.8	96.2%
DIA [mmHg]	69	93.1	127	11.6	76.9%
Pulse [1/min]	60	69.9	82	4.7	0.0%
HAP [mmHg]	95	116.1	152	10.6	96.2%
PP [mmHg]	27	69.3	125	23.2	79.5%

Afternoon (12:00-00:00)
 Measurements: 78 - Arrhythmias detected: 0

	Min	Average	Max	SD	> Limit
SYS [mmHg]	131	159.6	201	18.2	96.2%
DIA [mmHg]	67	93.9	125	11.6	78.2%
Pulse [1/min]	62	70.2	96	4.9	0.0%
HAP [mmHg]	90	115.8	144	10.5	94.9%
PP [mmHg]	28	65.6	115	20.2	73.1%

Difference morning/afternoon

SYS	1.7%	Fall in the afternoon
DIA	0.9%	Rise in the afternoon
Pulse	0.4%	Rise in the afternoon
HAP	0.3%	Fall in the afternoon
PP	5.3%	Fall in the afternoon

Print...

Print...

The measurements of the total, morning and afternoon period are evaluated separately.

The total of the readings in each period and the number of arrhythmias detected are displayed.

The following values are displayed in the individual columns:

- Min:* Smallest value in the corresponding interval
- Mean:* Arithmetic mean in the corresponding interval
- Max:* Largest value in the corresponding interval
- StdDev:* Standard deviation in the corresponding interval
- > Limit:* Percentage part above the specified limits Percentage rise/fall in the afternoon is displayed.

5.6.1 “Print...” button (see Fig. 59)

Printout of the SYS/DIA profile and the pulse profile as well as the statistics.

If “PDF file” was selected in the print settings (chapter 5.7.3), a PDF file is created. The file name of this PDF file is `medi_pat#_YYYYMMDD_sys.pdf`.

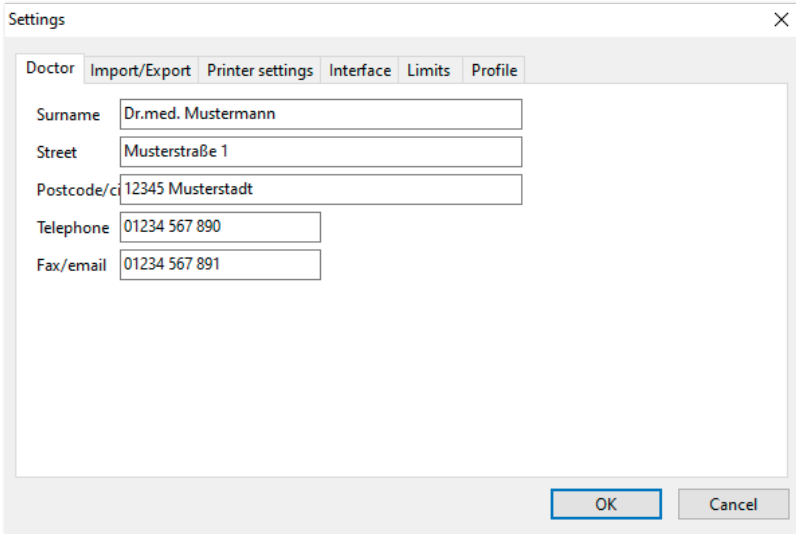
pat# = Patient number
YYYYMMDD = Date of measurement
sys = Identification letter for SYS/DIA

5.7 Button

“Settings...” in the “Patient” tab

5.7.1 “Physician” subtab

Fig. 60



The screenshot shows a 'Settings' dialog box with a close button (X) in the top right corner. The 'Doctor' subtab is selected, and the 'Physician' subtab is active. The form contains the following fields:

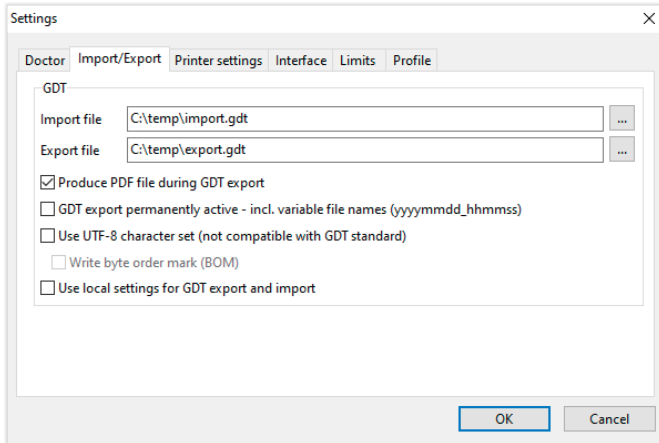
Field	Value
Surname	Dr.med. Mustermann
Street	Musterstraße 1
Postcode/ci	12345 Musterstadt
Telephone	01234 567 890
Fax/email	01234 567 891

At the bottom right of the dialog box, there are two buttons: 'OK' and 'Cancel'.

In the “Physician” subtab, the personal data of the attending physician is entered as the basis for the footer in the printout.

5.7.2 “Import/Export” subtab

Fig. 61



When using a practice EDP that supports the GDT interface, the path and file names for the export or import file are specified here. The buttons next to the input fields for import and export files give you direct access to the Windows directory structure.

Example: c:\prax_edv\import.gdt

Import file = Export file of the practice EDP

Export file = Import file of the practice EDP

The GDT import takes place automatically when the program starts or manually by clicking on the “Export/Import -> Import GDT” button if there is a valid GDT import file in the specified directory.

The GDT export only takes place if the patient imported from the practice EDP is active. The export takes place automatically when the program is exited (provided measurement data was read in from the device during the current program session) or manually at any time by clicking on the “Export GDT” button in the “Measurement data” tab.

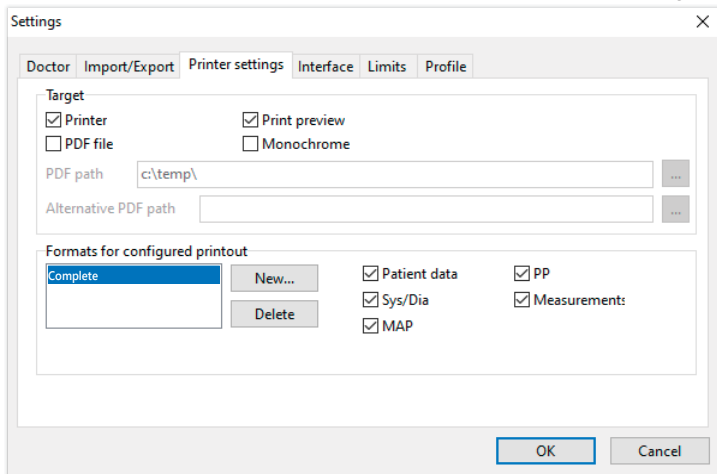


The data export is deactivated if the patient has changed after the automatic import. It will be reactivated when that patient is re-selected. The data export is also deactivated if no import has previously taken place.

For more information on the available options “Create PDF file parallel to GDT export”, “GDT export permanently active” and “Use UTF-8 character set” see 3.4.2.

5.7.3 “Print settings” subtab

Fig. 62



In the “Print settings” tab, you specify whether the printout is to be output in paper form, as a screen printout and/or as a PDF document after the respective [Print...] buttons have been pressed in the program sequence.

If “Printer” is selected, the Windows print dialogue is displayed when the [Print...] button is pressed in the program flow.

If “Print preview” is also selected, the print preview is displayed before printing.

If “PDF file” is selected, a PDF file will be created. The file name of this PDF file is application-specific and is described in more detail in the individual applications.



At least one medium “Printer” or “PDF file” must be selected.

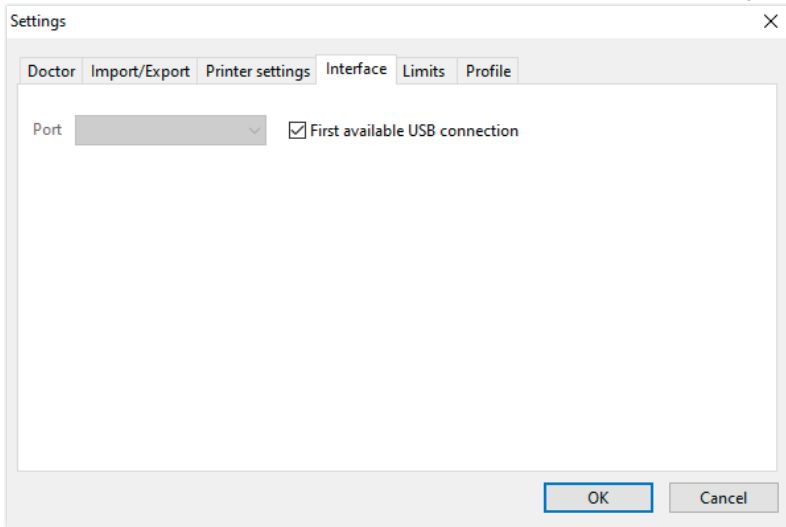
If the option “Monochrome” is selected, the printout will be monochrome. By clicking on the “Configured printout” printer icon, the printout format configured here is used and only the pages selected here are printed.

Fig. 63



5.7.4 “Interface” subtab (see Fig. 59)

Fig. 64



Specify here how the connection between the blood pressure monitor and the PC is established.

If the “First available USB port” option is active, the first FTDI USB port under Windows is used for data transfer. If multiple FTDI USB ports are installed, unneeded ports should be disconnected from the computer or the option disabled.

If the “First available USB port” option is not active, the serial interface (COM) or USB port selected in the port list is used for data transfer.

5.7.5 “Limits” subtab

Fig. 65

Section	Parameter	Value
Total	Systole	135
	Diastole	85
	Pulse	100
	MAP	100
	PP	50
Morning	Systole	135
	Diastole	85
	Pulse	100
	MAP	100
	PP	50
Afternoon	Systole	135
	Diastole	85
	Pulse	100
	MAP	100
	PP	50
Weight	BMI	25.0

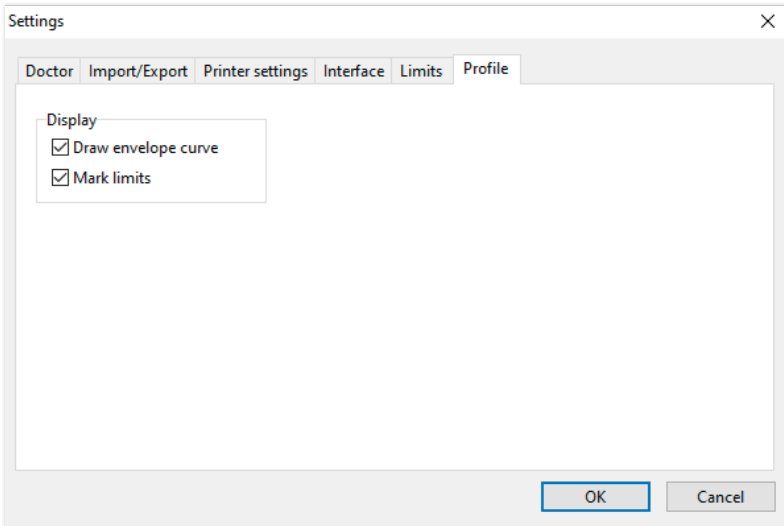
In order to enable an individual evaluation, the limit values for the individual periods can be defined. The setting of the limit values for morning and afternoon refer to the morning and afternoon interval times.

5.7.6 “Profile” subtab

In the profile displays (“Profile Sys/Dia, MAP, PP” tab) an envelope curve (connecting line between the individual measurement points) is drawn by default and the limit values are displayed as horizontal lines.

Both envelope curve and limit lines can be hidden here.

Fig. 66

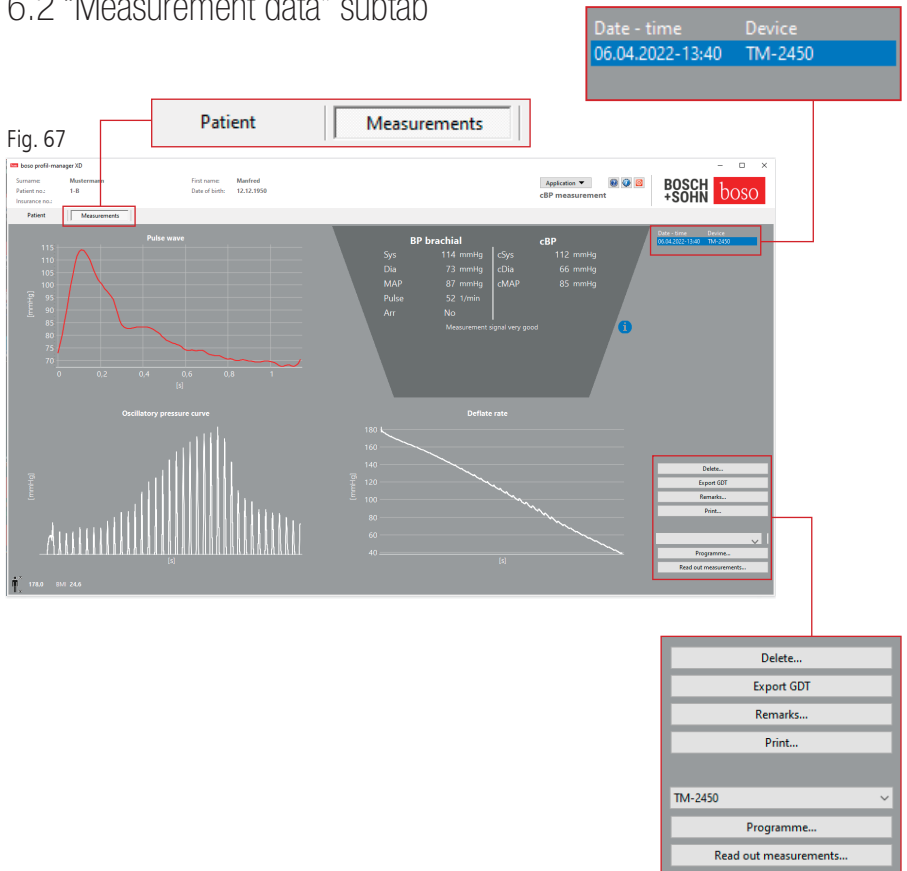


6 “cBP measurement” application

6.1 “Patient” tab

See section “2.1 Patient tab - valid for all applications”.

6.2 “Measurement data” subtab



In the “Measurement data” tab, measurements that have been carried out can be viewed and new measurements can be carried out. To view cBP measurements that have already been taken, select the desired cBP measurement in the “Date - Time” field.

6.2.1 BP brachial + cBP (optional)

The following parameters are displayed in the screen display (see Fig. 67).

see Fig. 67

BP brachial		cBP	
Sys	114 mmHg	cSys	112 mmHg
Dia	73 mmHg	cDia	66 mmHg
MAP	87 mmHg	cMAP	85 mmHg
Pulse	52 1/min		
Arr	No		

Measurement signal very good

BP brachial

The measured brachial blood pressure

Sys

Systolic blood pressure of the upper arm, shown in red >140 mmHg

Dia

Diastolic blood pressure of the upper arm, shown in red > 90 mmHg

Pul

Heart rate in bpm

Arr

Indication of whether there was an irregularity in the pulse rate of more than 25% during the measurement, red if an arrhythmia is present

cBP (optional)

Central blood pressure

cSYS

Systolic blood pressure (central)

cDIA

Diastolic blood pressure (central)

cMAP

Mean arterial pressure (central)

6.2.2 "Delete" button (see Fig. 67)

Measurements that have already been carried out are irrevocably deleted.

6.2.3 “Export GDT” button (see Fig. 67)

Manual generation of the GDT export file. Only available if the active patient has previously been GDT imported.

6.2.4 “Program...” button (see Fig. 67)

Starts the assistant for programming the TM-2450 as described in chapter 4.2.7. After programming the device, a manual measurement can be performed by pressing the START/STOP button. A running measurement can be aborted at any time by pressing the START/STOP button on the device.



There may only be one measurement in the device.

The USB connection must be disconnected in order to start a measurement.

6.2.5 “Read measured values” button (see Fig. 67)

Before pressing the “Read measured values” button, the measuring device must be connected to the PC connection cable. The measurement data is then transferred from the connected measuring device and displayed.



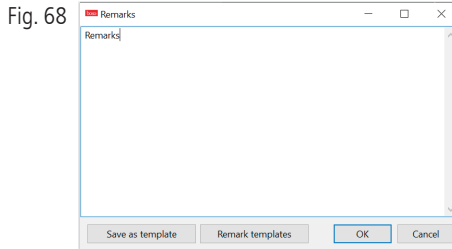
The parameters of the cBP are to be understood as a useful supplement in this process. It helps to identify high blood pressure, to make therapy decisions and to monitor success.



A sole decision of the physician based on the parameters of the cBP does not take place. This would be a violation of the applicable guidelines for hypertension.

6.2.6 “Remarks...” button (see Fig. 67)

A remark can be added to a measurement by clicking in the “Remark” field (or via the button).



Recurring remarks can be saved as a template using the “Save as template” button. Saved remark templates can be easily inserted into a remark field at any time using the “Remark templates” button.

Measurements with remarks are marked with a “B” in the “Date - Time” field.

6.2.7 “Print” button (see Fig. 67)

Generates a printout of the current measurement. If “PDF file” was selected in the print settings, a PDF file is created. The file name of this PDF is: pwa_pat#_YYYYMMDD_HHMMSS.pdf

Where

pat# =

Patient number

YYYYMMDD_HHMMSS =

Date and time of the measurement

m =

Identification letter for measurement

7 Warranty policy

Irrespective of statutory warranty rights, bosco guarantees that the software data carrier will be free from material and processing defects within 90 days of the date of purchase.

Based on the guarantee promise given above, bosco is obliged to replace the data carrier with the software it contains under the following conditions:

- the customer/buyer notifies bosco in writing of the fault within 90 days of the date of purchase

or

- the customer/buyer returns the defective data carrier to the retailer within 90 days or directly to bosco at the following address:

BOSCH + SOHN GmbH u. Co. KG
Bahnhofstr. 64
72417 Jungingen, Germany

bosco does not assume any guarantee, either express or implied, that goes beyond the guarantee promise given above.

8 Limitations of liability

- a) The software is made available to you on the basis of the current state of development.
- b) Irrespective of the provision in Chapter 6, boson and its dealers assume no liability for risks relating to the results and performance of the software. Our liability is excluded for indirect damage, consequential damage, loss of profit, damage due to lost or damaged data or for any other commercial or economic loss.
- c) The above exclusion of liability does not apply to liability under the Product Liability Act and insofar as we or our vicarious agents acted with intent or gross negligence.

9 Obligation to report incidents

A serious incident shall be reported to the manufacturer and to the responsible authority of the Member State in which the user and/or patient is established.

A "serious incident" means an incident that directly or indirectly had, could have had, or may have had any of the following consequences:

1. the death of a patient, user or other person,
2. the temporary or permanent serious deterioration in the state of health of a patient, user or other person,
3. a serious risk to public health.

Reports of serious incidents should be directed to:

Email: vigilanz@boso.de
Fax: +49 (0) 7477 9275 56

Excerpt from the GDT record description

The record types required to implement the GDT interface of this software and the field identifiers they contain are described below:

Record type 6302 "Request new examination"

Field 8000:	Record identification
8100:	Record length
8315:	GDT ID of the recipient
8316:	GDT ID of the sender
8410:Testident	(BDM00: Direct access to patient measurement BDM01: Direct access to 24h measurement BDM02: Direct access to ABI/PWV measurement
9218:	Version number GDT
3000:	Patient number
3101:	Patient's last name
3102:	Patient's first name
3103:	Patient's date of birth
3105:	Insurance number
3106:	Patient's place of residence
3107:	Patient's street
3110:	Patient's gender (1 = male, 2 = female)
3622:	Patient's height (cm)
3623:	Patient's weight (kg)

Record type 6310 “Transfer data for an examination”

Field 8000:	Record identification
8100:	Record length
8315:	GDT ID of the recipient
8316:	GDT ID of the sender
9218:	Version number GDT
3000:	Patient Number/Patient ID
8402:	Device and process-specific map
6200:	Date of examination
6228:	Result table text, formatted
6302:	File archiving ID
6303:	File format
6304:	File content
6305:	Reference to file

