Powerful software for computer-assisted blood pressure control and observation of therapy.

BOSCH +SOHN boso

PROFIL-MANAGER XD

User manual
Installation instructions

Compatible with
boso ABI-system 100 | boso ABI-system 100 PWV
boso TM-2450 | boso TM-2430 PC 2 | boso medicus system
boso medicus PC 2 | boso medilife PC 3

Version 6.0

EN

CE 0124

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1 installation CD

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Technical data

Minimum operating requirements:
- 1 GHz • 1 GB RAM • 100 MB free hard disk space
- USB 2.0 interface • Windows 8 • 1920 x 1080 pixels

Accuracy of the displayed values:

Systole, diastole, pulse = Accuracy of the measuring devices used

ABI = Accuracy of the measuring devices used for the systolic pressure (2 decimal places)

PWV = ±5% (1 decimal place)

Intended use

Software, utilised for
- Display of measurements determined by boso measuring devices
- Archiving of measurements in its own database
- Data exchange with clinic data processing systems via GDT interface
- Programming of 24-hour measuring devices (interval limits, interval time, maximum inflation pressure)
- Control of ABI measurement systems (start and termination of a measurement)

Contraindication

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

1.1 Before installation

You have chosen boso profil-manager XD, a software solution which gives you optimum results with minimum input time. boso profil-manager XD has been deliberately designed to be operated without the usual menu structure based on individual registries. This is why the user manual also refers to individual windows and program parts as registries.

1.1.1 Data backup

To avoid losing data, you should back up the "profman5.fdb" file from the C:\ProgramData\Boso\profmanXD\ sub-directory at regular intervals.

1.1.2 Operating the program

The program is operated by the mouse.

PC requirements

The computer used to assess the ABI/PWV measurement must comply with the latest version of European standard EN 60601-1.

This user manual for the use and installation of the boso profil-manager XD applies to version 6.0.0.0 and above. Please refer to the readme.txt file on the installation CD for new information. The drive letters in this user manual are simply examples:
C:\ for the local hard drive
D:\ for the CD/DVD drive

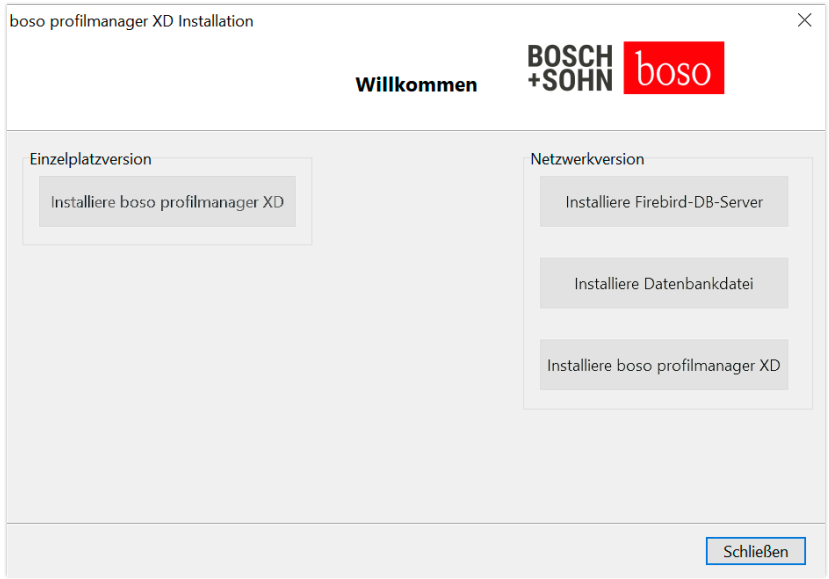
The path data corresponds to a standard single-user installation under the German Windows 10 (64-bit) operating system and may be different in other operating systems or language versions. Microsoft and Microsoft Windows are registered trademarks of the Microsoft Corporation.

1.2 Installation of the boso profil-manager XD

To install boso profil-manager XD, start file D:\BosoInst.exe manually or automatically via the autostart function which runs when you have inserted the CD.

Make sure that you have administrator rights when installing the program. (If in doubt, start the "BosoInst.exe" program with the right mouse button, "execute as administrator".)

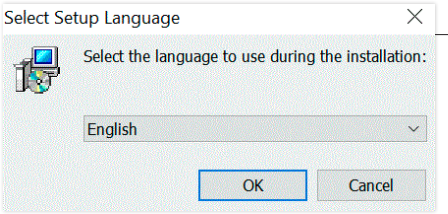
The following selection screen (in German) will appear as soon as the program has started:



Choose either "Einzelplatzversion" (single-user version) or "Netzwerkversion" (network version).

1.2.1 Single-user version

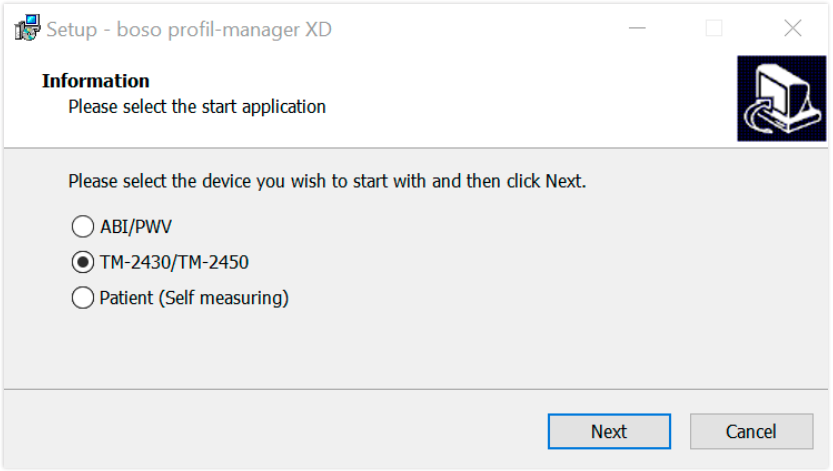
The single-user version is the correct choice if you are only going to run the program on one computer. In this case you do not need to install a separate Firebird database server (an embedded Firebird is used). Follow the installation assistant instructions.
Select your preferred language for installation:



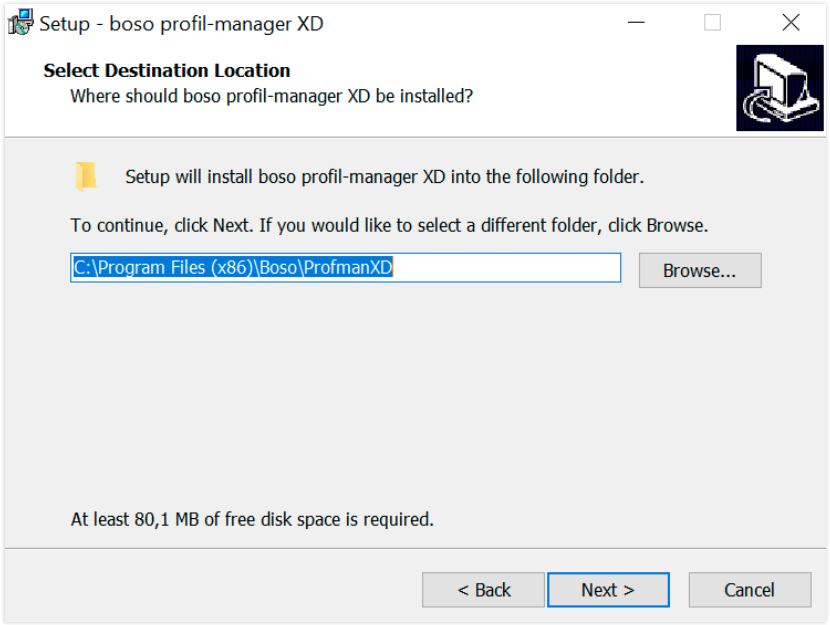
The available languages are:

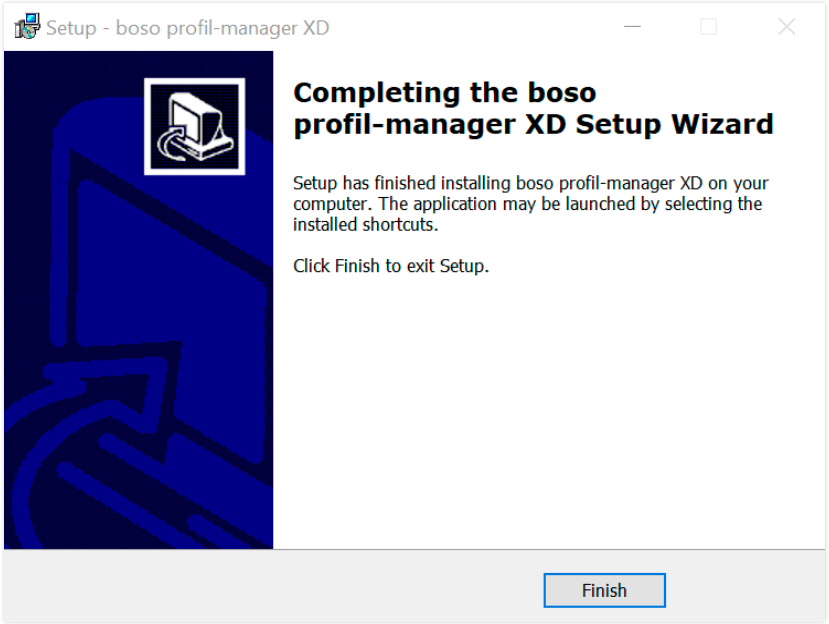
- German	- Finnish
- French	- Spanish
- Italian	- Hungarian
- Czech	- Slovenian
- Russian	- Danish
- Chinese	- Polish
- Slovakian	- Indonesian

As the program can be used with all current boso PC devices, in the next screen you must select the type of device to be activated when starting the program for the first time.
After installation you can switch between device types at any time while using the program.



You can change the target folder for installation individually, but in most cases the default folder is used unchanged:





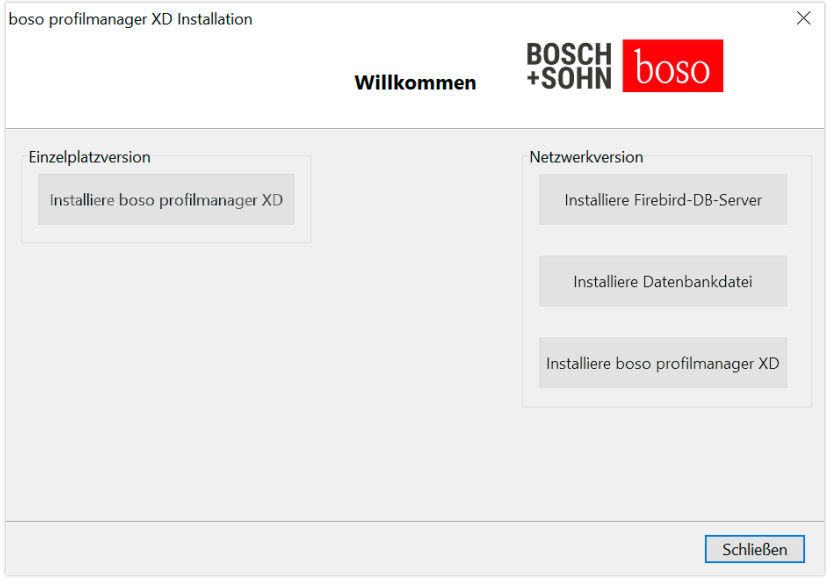
Once you have successfully installed the single-user version of boso profil-manager XD, click on the "Finish" button to close the installation screen.

1.2.2 Network version (screenshot in German)

The network version is the correct choice if you are going to run the program on multiple workstations in an IT network.
Here the database can be stored at any location in the IT network.

Installation in an IT network that includes other devices can lead to previously unknown risks for patients, operators or third parties. The organisation responsible must determine, analyse and control these risks. The following changes to the IT network can lead to new risks and therefore make additional analyses necessary:

– Change to the IT network configuration (e.g. updating the version of Firebird, opening a TCP port, antivirus reconfiguration...)
– Connecting additional elements to the IT network
– Removing elements from the IT network
– "Updating" devices connected to the IT network
– "Upgrading" devices connected to the IT network



1.2.2.1 Installing the Firebird database server

In order to run the network version of boso profil-manager XD, the Firebird database server must be installed on the computer where the database is to be stored.
Click on the "Installiere Firebird-DB-Server" (Install Firebird DB server) button to install the Firebird database server.

After selecting the language, follow the instructions given by the installation assistant and accept all the default settings.

1.2.2.2 Installing the database file

The "profman5.fdb" database file can be stored at any location in the network.

Make sure that the computer in which the database is to be located is running a current Firebird server (version 2.5 or above), that the TCP port 3050 is open for access when the firewall is active, and that access to the database and the database server is not blocked by an anti-virus program.

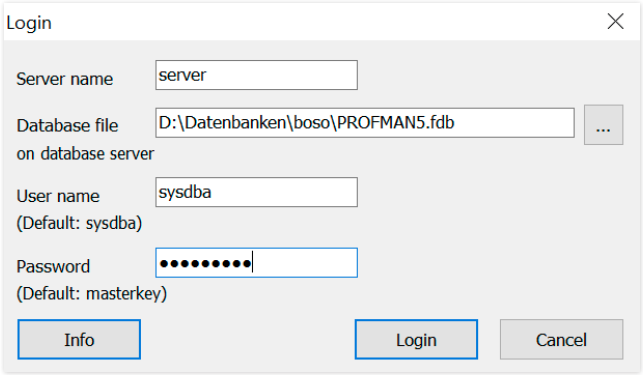
1.2.2.3 Installing boso profil-manager XD

You can install boso profil-manager XD on any computer in the network by clicking the "Installiere boso profilmanager XD" (Install boso profil-manager XD) button.

Follow the instructions given by the installation assistant as described for the [single-user version] in chapter 1.2.1.

1.2.2.4 Launching the network version for the first time

When you launch the network version for the first time, you will see a login window to register with the Firebird database.



The login data you enter here will be stored in the "profman.ini" file in the C:\Programme\Boso\ProfmanXD\ directory and can be modified if necessary at any time, for instance if the database is moved to another location in the network.

Server name:
Name of the server in which the database is located.

Database file:
Drive, path and name of the boso profil-manager XD database file from the server's perspective.

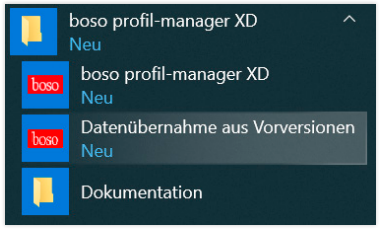
User name:
Login information for the current Firebird database server. The default name is "sysdba". Login information may be different if Firebird has already been installed.

Password:
Login information for the current Firebird database server. The default password is "masterkey". Login information may be different if Firebird has already been installed.

1.3 Converting data from previous versions

Use the Konverter.exe program to convert existing data from earlier Firebird databases.

Launch the program either via Windows Explorer from the directory path C:\Programme\Boso\ProfmanXD\ or via the Windows start button, selecting the program "Datenübernahme aus Vorversionen" (Transfer data from previous versions) under the "boso profil-manager XD" program group.



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

Enter a user name and password to register with the Firebird database server. The default username is "sysdba" and the default password is "masterkey".

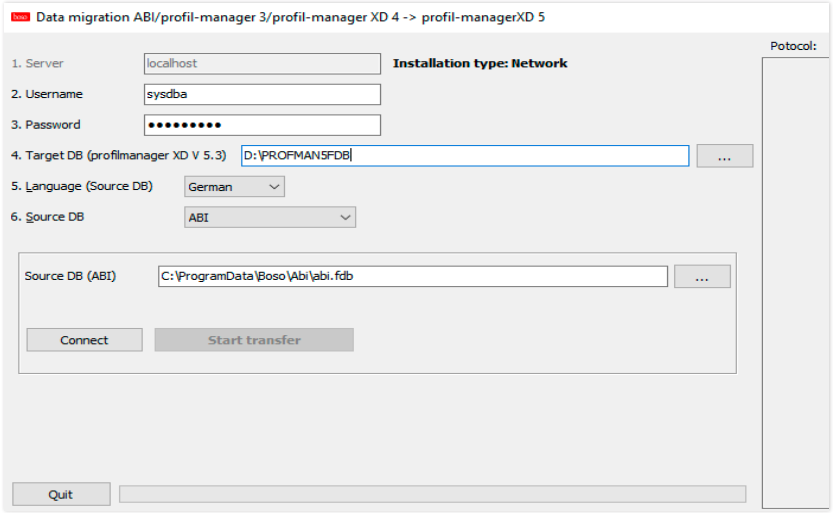
Select the storage location for the boso profil-manager XD file in the "Target DB (profil-manager XD V 5.1)" field.

Select the language of the source DB.

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

Select the storage location of the database you want to convert. Click on the "Connect" button to connect to the source database.

Once you have established a connection with the source database, start transferring data by clicking on the button of the same name ("Start transfer").



If you transfer data successively from multiple databases, the separate sets of data are brought together in the new database.
Measurements for a specific patient are only brought together if the surname, first name and date of birth are the same. If the patient numbers are different, the patient number of the target database is retained.

If the surname, first name and date of birth do not match, or if these fields are empty or out of date, a new patient record will be created. The patient number is retained unless it already exists in the target database, in which case a new patient number will be created.
All patients with mismatches are transferred to a list. The data can be updated before being transferred. Missing or out-of-date data will not be transferred.

1.4 Installation instructions for the USB cable for boso TM-2430 PC 2

The USB driver is pre-installed during the installation (standard). The USB connection cable supplied only needs to be connected to a free USB port. The cable is then automatically recognised and installed.

Information regarding the boso TM-2430 PC 2:
If the driver was not pre-installed, you must execute the file

dpinst_32bit.exe/dpinst_64bit.exe

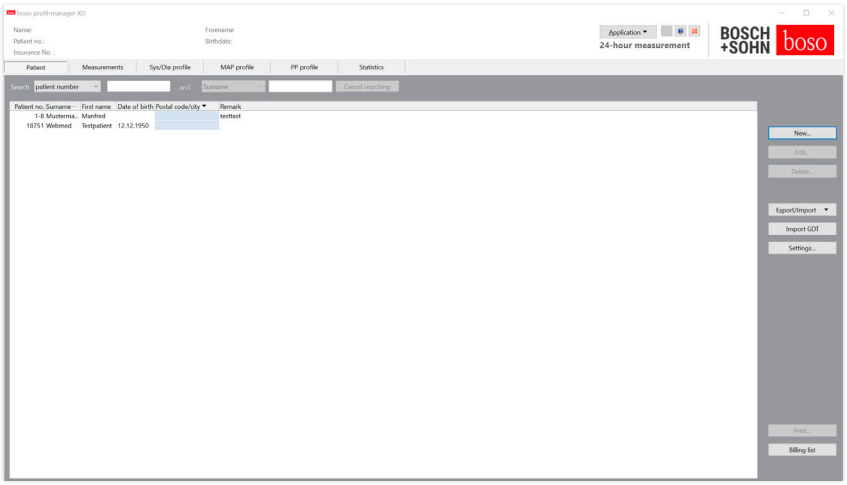
(present after installation in the directory C:\Programme\Boso\profmanXD\ftdi\) as administrator and then plug the USB cable into a free USB port.

1.5 Driver installation for boso TM-2450 in Windows 8/8.1

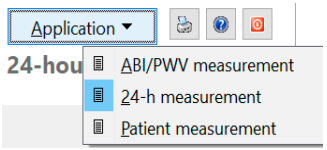
In Windows 8/8.1, this must be installed manually from the CD (D:\Treiber\TM2450\).

Instructions on how to do this can be found at:
D:Driver\TM2450\

2 Start



After starting profil-manager XD by clicking on the "boso profil-manager XD" icon, select the part of the program you wish to run in the light of the device application you are currently using:



Applications with data already stored are indicated by the symbol "▤". Applications with no data at present are indicated by the symbol "□".

If you switch from one application to another for a selected patient, the "Measurements" registry is automatically selected. This means that measurements from various applications provide you with an overall view of all measurements for a particular patient.

Accessing the help function

Press the F1 key or the [Help] button to call up these and other instructions for use in PDF format at any time.

2.1 Patient registry

– for all applications

Click on a patient to select him or her. Patients can be sorted by clicking on the header of the relevant column.
Use the "Restore column order" function to go back to the original sorting by patient number. To do this, right-click in the header row of the patient table. You can search by name via the "Search" function.

2.1.1 "New…" button

This sets up a new patient. The name and patient number fields must be completed. The patient number is generated by the system (consecutive number with the addition "-B").
To change the patient number generated:
Hold down the "Ctrl" key on the keyboard and use the mouse to click on the "Patient no." field.

When operating in the clinic environment, it is strongly recommended to create new patients exclusively in the clinic data processing software.

2.1.2 "Edit…" button

This alters an existing patient's personal data.

2.1.3 "Delete…" button

This deletes a patient.

The process is irreversible: all data (including measurements) from all parts of the application are deleted and cannot be recovered.

2.1.4 "Export/Import" button

2.1.4.1 "Export Excel"

"Export Excel" exports data for the currently selected patient (from the current ABI, 24-hour, patient measurement application) in Excel-readable .xls format. You can choose whatever file name and storage location you like.

2.1.4.2 “Export patient (XML)”

“Export patient (XML)” exports data for the currently selected patient in profil-manager XD-readable .xml format.

The transfer path from the transfer file settings is used for incorporation into the clinic’s data processing system (see next chapter, “Settings…” button). The file name is made up of the active application and the patient number.

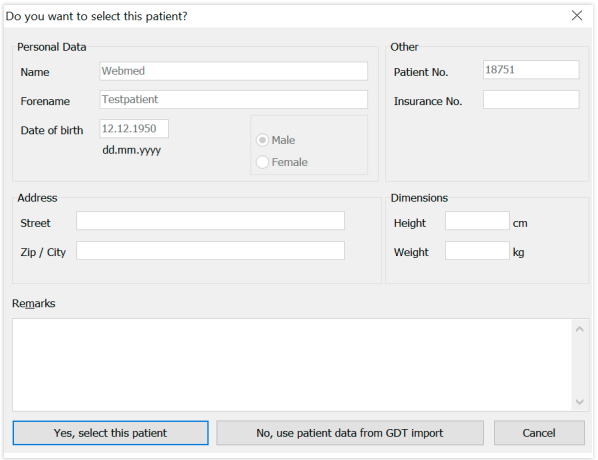
For example, “2430_10.xml” stands for patient data for the patient with patient number 10 from the 24-hour measurement application.
2430_#.xml stands for data from the 24-hour measurement
ABI_#.xml stands for data from the ABI measurement
medicus_#.xml stands for data from patient measurement
medicus_#-M.XML stands for data from the boso app

2.1.4.3 “Import patient (XML)”

“Import Patient (XML)” imports the data from a selected patient, for example, from the boso app.

2.1.5 Import GDT

The GDT import file, if available, is read and the included patient is selected or created. If a patient with the imported patient number already exists, the following screen appears:



The button "Yes, select this patient" selects the indicated patient.

With the button "No, use patient data from GDT import" all existing measurements will be assigned to the patient from the GDT import file.

2.1.6 “Settings…” button

The settings are explained in the sections dealing with particular applications (chapters 3–5) as they are application-specific.

2.1.7 “Print…” button

Patient data are displayed on the screen. The data can then be printed out using the selected printer.

The Windows standard printer is the default for print-outs.

If you selected “PDF file” in the printer settings, a PDF file will be created. The name of this PDF file is pmXD_pat#.pdf

Pat# = patient number

2.1.8 “Billing list” button

This creates a summary of the number of measurements in the currently selected application that have been performed within a given time period (not available for patient measurement).
For example, this provides a simple indication of how many 24-hour measurements were performed in the first quarter.

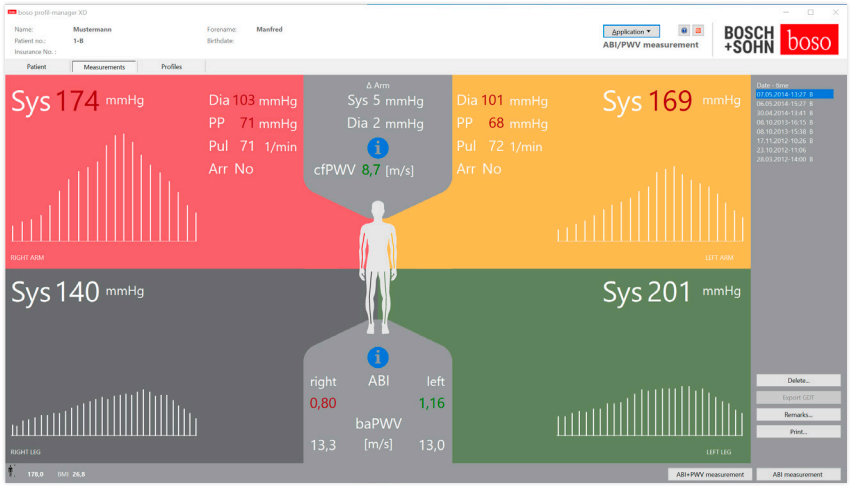
If you selected “PDF file” in the printer settings, a PDF file will be created. The name of this PDF file is pmXD_cl.pdf.

3 “ABI/PWV measurement” application

3.1 “Patient” registry

See section "2.1 Patient registry, for all applications". See chapter 3.4 for "Settings" button.

3.2 “Measurements” registry



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

Sys Upper arm systolic blood pressure, with measurements >140 mmHg in red

Dia Upper arm diastolic blood pressure, with measurements >90 mmHg in red

PP Pulse pressure = difference between systole and diastole, with measurements >54 mmHg in red

Pul Pulse in 1/min

Arr Indication of whether a pulse irregularity of over 25% was observed during the measurement. Display in red indicates arrhythmia

ABI Ankle-brachial index = ratio of the systolic pressure measured in the leg and the higher systolic pressure measured in the arm. Display in red indicates an ABI < 0.9 [default]

baPWV (optional) Measured pulse wave velocity brachial-ankle. Since there is no exact limit but only a grey area of 14 to 18 m/sec, the baPWV value is shown in neutral black only.
In some cases, the limit value is also determined individually depending on the sex, age and blood pressure of the patient.

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

The patient’s height must be entered as this information is needed to calculate PWV.

Sys Systolic blood pressure in the ankle

Diff Arm Sys Difference between the systolic values in the left and right upper arms, with results > 10 mmHg displayed in red

Diff Arm Dia Difference between the diastolic values in the left and right upper arms, with results > 10 mmHg displayed in red

Clicking on one of the oscillation profiles enlarges the selected profile. The “Pulse level/time” registry shows the course of oscillation over the time axis. The “Pulse level/cuff pressure” registry shows the course of oscillation over cuff pressure.

3.2.1 “Delete...” button

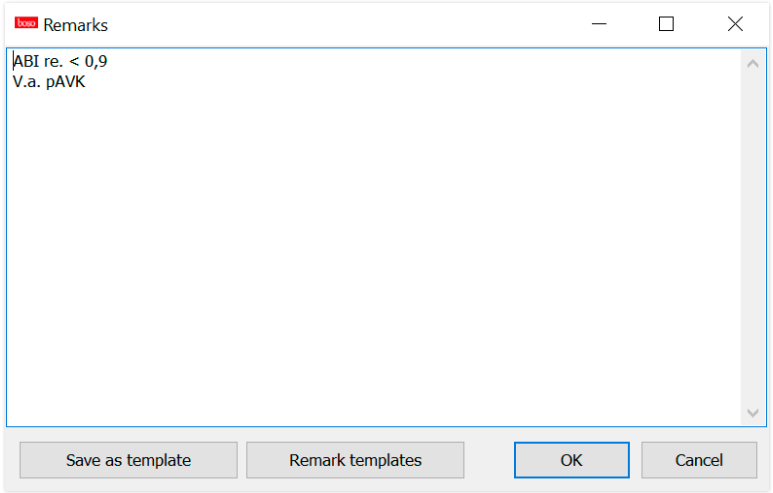
Measurements that have already been performed can be irrevocably deleted by this button.

3.2.2 “Export GDT” button

This generates the GDT export file manually. Only available if the GDT import of the active patient has already been performed.

3.2.3 “Remarks. . .” button

Click in the “Remarks” field (or the button) to add a remark to a measurement.



Remarks that are made frequently can be stored as templates using the “Save as template” button. You can use the “Remark templates” button to easily insert stored remark templates into a remark field at any time.

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

3.2.4 “Print. . .” button

This produces a print-out of the current measurement.

If you selected “PDF file” in the printer settings, a PDF file will be created. The name of this PDF file is ABI_pat#_YYYYMMDD_HHMMSS_m.pdf.

pat# =	patient number
YYYYMMDD_HHMMSS =	date and time of measurement
m =	measurement reference letter

3.2.5 “ABI measurement” button

This initialises the boso ABI system 100 and starts a new measurement. You can cancel a measurement which is being performed at any time by using the “Cancel measurement” button or pressing the STOP key on the device. Once the measurement of a limb has been completed, the “Save measurement” key is activated. You could store the measurement at this stage (for example, if the patient has a limb missing).

Once all measurements on four limbs have been completed, a green border appears around the active “Save measurement” button. This indicates that the measurement has been successfully completed and can be stored.
If an error occurs during a measurement, the following error messages appear in the corresponding measurement window:

(82) Measurement error/no results display -> retry measurement

If no reading is displayed for blood pressure, check the cuff and tubes and then retry. If no reading is displayed the second time, this can indicate a circulation disorder or medial sclerosis. Further investigations are recommended here.

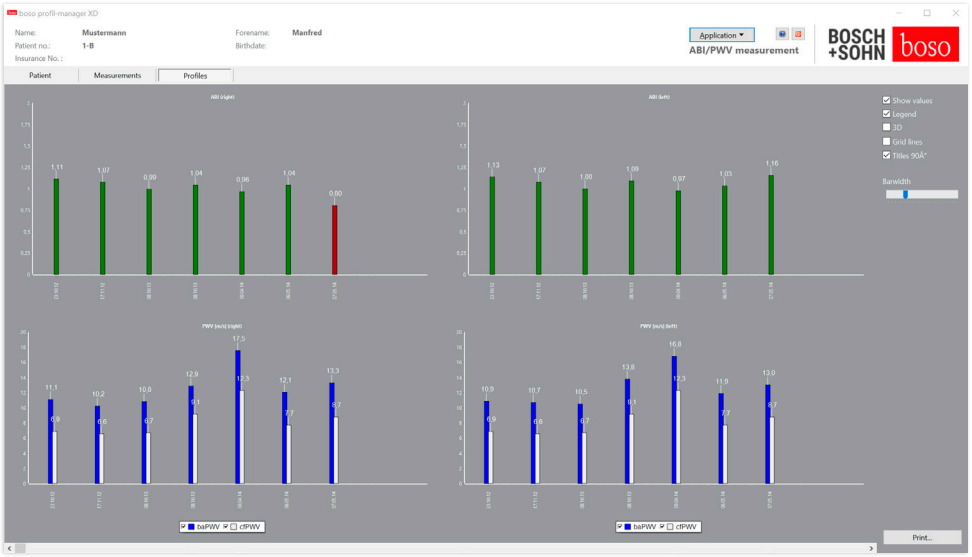
(83) Connect cuff

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

3.2.6 “ABI+PWV measurement” button (optional)

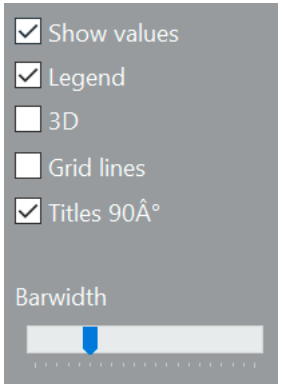
This automatically performs a PWV measurement 10 seconds after completion of the ABI measurement described under 3.2.5.
A green border appears around the “Save measurement” button once the PWV measurement has been completed. This indicates that the PWV measurement has been successfully completed and can be stored.

3.3 “Profiles” registry



The (optional) ABI/PWV values of all measurements are presented in the form of bar charts in the “Profiles” registry. The ABI colour display is as per the setting under “Classification” (red: ABI < 0.9).

Various parameters are available to alter the optical presentation of the profile:



Show values (standard):	ABI values are displayed above the bars.
Legend:	The legend for the readings is displayed in the diagram.
3D:	The bars are displayed in 3D.
Grid lines:	Grid lines are shown in the coordinates system.
Titles 90°:	The title of the x-axis is rotated through 90°.

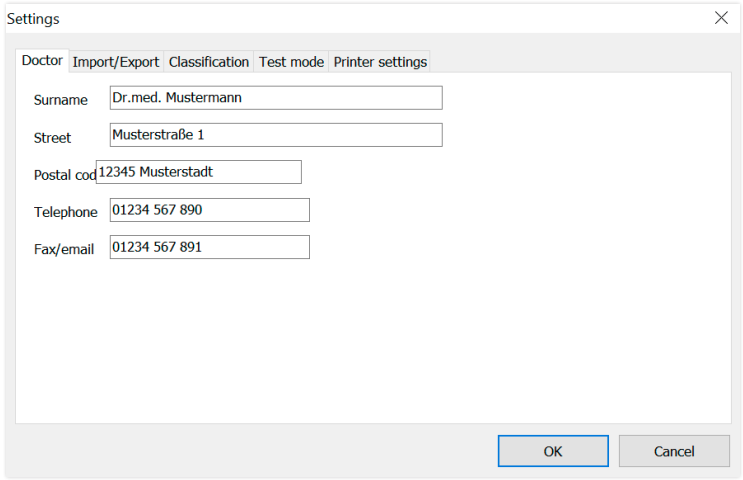
3.3.1 “Print…” button

This produces a print-out of the profile display. If you selected “PDF file” in the printer settings, a PDF file will be created. The name of this PDF file is ABI_pat#_p.pdf.

pat# = patient number
p = profile reference letter

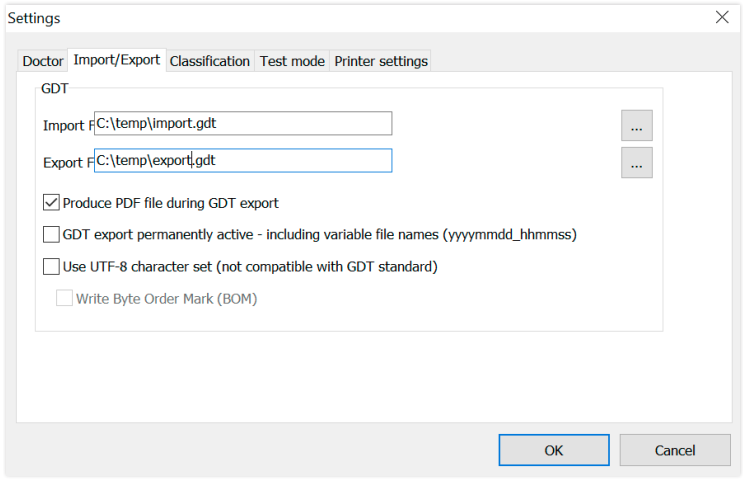
3.4 “Settings” button in “Patient” registry

3.4.1 “Doctor” sub-registry



The personal details of the doctor treating the patient are entered in the “Doctor” sub-registry and used to produce the footer in the print-out.

3.4.2 “Import/Export” sub-registry



If you are using a clinic data processing system that supports the GDT interface, this is where the path and file names for export and import files are set. You have direct access to the Windows directory structure via the buttons next to the input fields for import and export files.

Example: c:\prax_edv\import.gdt
Import file = clinic DP system export file
Export file = clinic DP system import file

GDT import takes place automatically when you start the program, or manually by clicking the “Export/Import -> Import GDT” button if a valid GDT import file is present in the relevant directory.

GDT export takes place only if the patient being imported from the clinic DP system is active. Export takes place automatically when the program is closed down (if measurements have been read in from the device during the current program session) or can be performed manually at any time by clicking the "Export GDT" button in the "Measurements" registry.

Data export is deactivated if another patient has been selected after automatic import. It is reactivated when this patient is reselected. Data export is also deactivated if no import has first taken place.

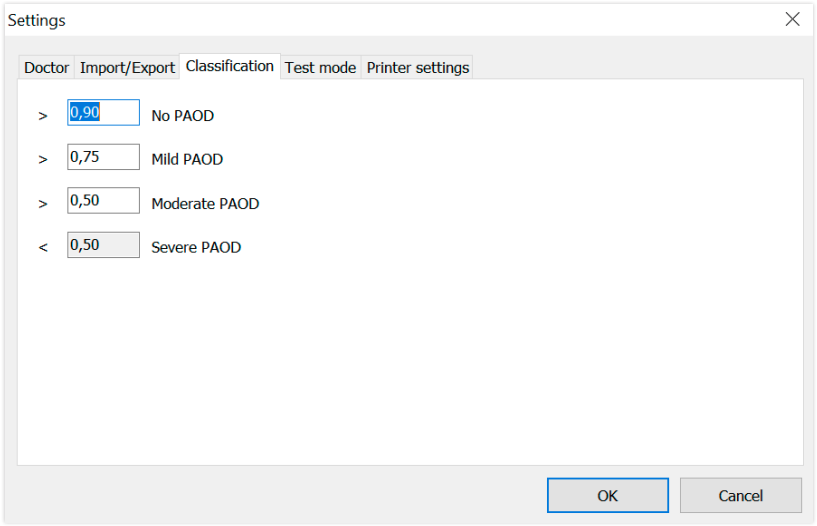
For certain applications (connection to HL7 in hospital operation), it may be necessary to activate GDT export permanently and name the export file in a variable way (Export.gdt -> yyyymmdd_hhmmss.gdt). For this, activate the option "GDT export permanently active - including variable file names”.

If this option is selected in the clinic environment, it must be ensured in particular that the active patient of the clinic DP system is identical to the exported patient.

If you select the "Produce PDF file during GDT export" option, a PDF file will be produced when the GDT export takes place.

To be able to also display special characters from certain foreign languages in the GDT, the UTF8 character set must be used. This is not part of the GDT standard and must be specifically selected via the option "Use UTF-8 character set".

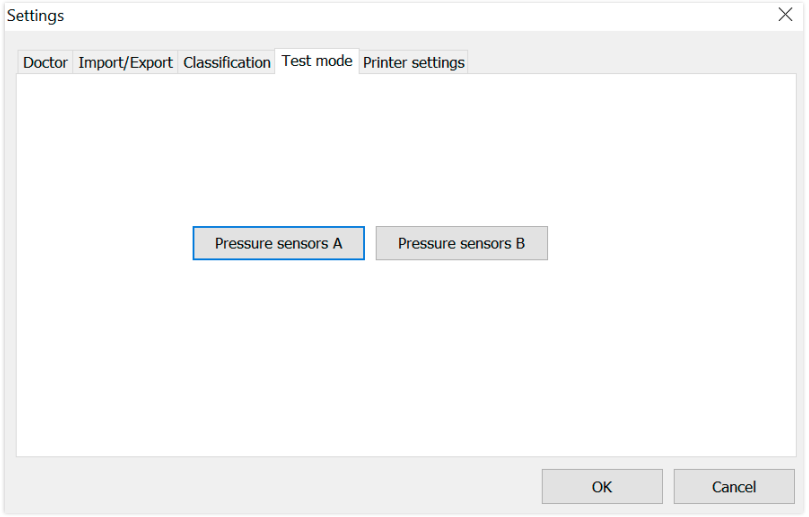
3.4.3 "Classification" sub-registry



Limits for ABI value classification can be amended here.

Modifications do not take effect until the program is restarted.

3.4.4 "Test mode" sub-registry



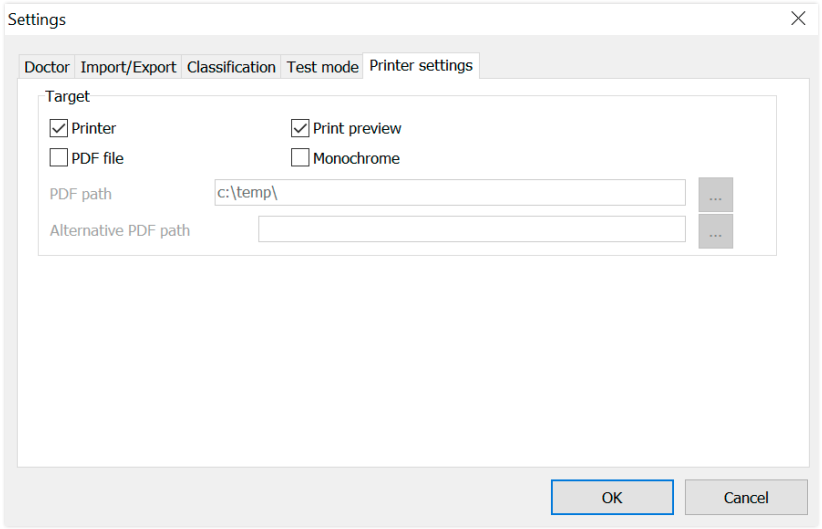
The test mode is activated using the "Pressure sensors A" and "Pressure sensors B" button. Clicking on the "Finish test" button ends test mode.

This function is needed for various purposes, for example, testing pressure during metrology tests.

(optional)
Special simulators are needed to perform functional tests of the device with the "PWV" option, and these tests must be carried out on the manufacturer's premises.

"Pressure sensors B" can be activated only in the case of serial number 466 20000 or higher.

3.4.5 “Printer settings” sub-registry



In the “Printer settings” registry you decide whether the print-out should be produced in paper form, as a screen print and/or as a PDF document, once the relevant [Print…] buttons have been clicked while the program is running.

If you select “Printer”, then the Windows print dialogue appears when you click on the [Print…] buttons while the program is running.

If you also select “Print preview” the print preview is displayed before printing.

If you select “PDF file”, a PDF file will be created. The name of this PDF file is constructed for the specific application in question, and is described in more detail in the individual applications.

You must select at least one medium “Printer” or “PDF file”.

If you select the “Monochrome” option, the print will be in black and white.

3.4.6 Error codes

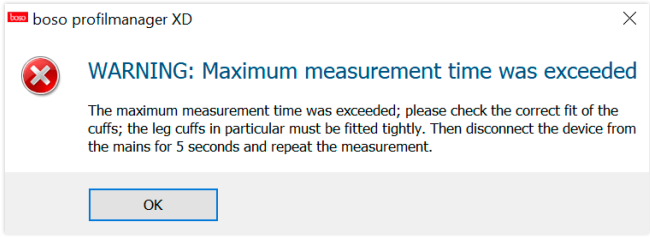
(82) Measurement error/no results display -> retry measurement

If no reading is displayed for blood pressure, check the cuff and tubes and then retry. If no reading is displayed the second time, this can indicate a circulation disorder or medial sclerosis. Here further investigations are recommended.

(83) Connect cuff

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

Warning: Maximum measurement time was exceeded.



This message appears after an excessively long measurement time; the maximum duration allowed is 150 seconds.
A cuff that is applied incorrectly and/or too loosely can prolong the measurement time and/or lead to repumping.
It is also important to ensure that the cuff does not directly touch the lounger. This can lead to jerky slipping of the cuffs on the lounger, which in turn leads to repumping. A protective paper underlay can help here.

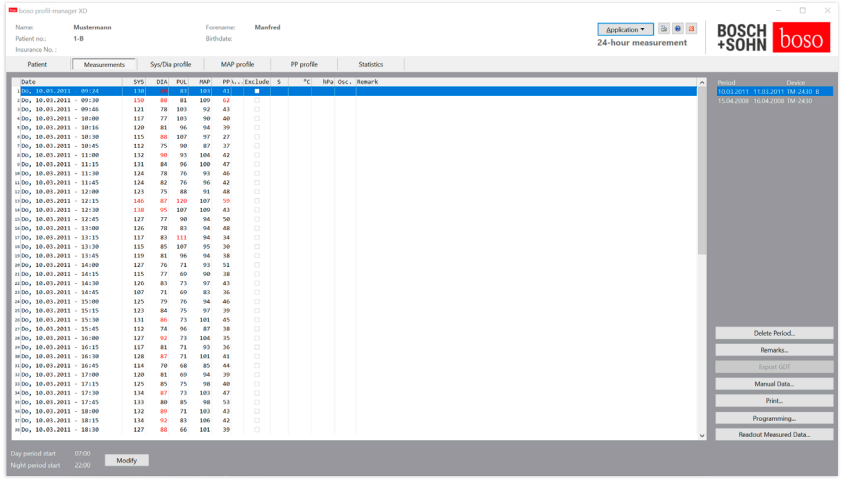
Disconnect the device from the mains for 5 seconds to resolve the problem. Should this problem immediately recur after the start of a new measurement, please send the device to the manufacturer to be checked.

4 “24-hour measurement” application

4.1 “Patient” registry

See section “2.1 Patient registry, for all applications”. See chapter 4.7 for “Settings” button.

4.2 “Measurements” registry



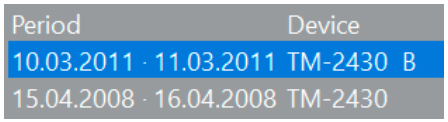
All measurements that have been read in to date for the selected patient are displayed here.

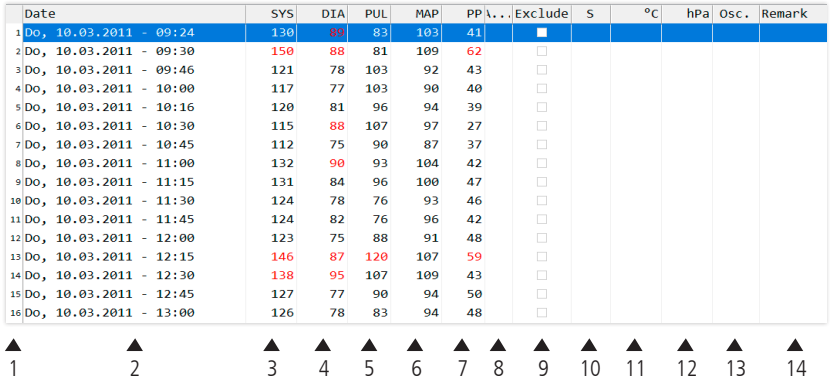
This is where the 24-hour measuring device is initialised and data are read out from the device.

A patient must be selected before you can switch to this registry. When the program starts, no patient is selected. If you have not selected a patient manually or imported a patient automatically via the GDT interface, you will see a help screen.

Both the period and the blood pressure meter with which the series of measurements was carried out are displayed.

Select the appropriate period.



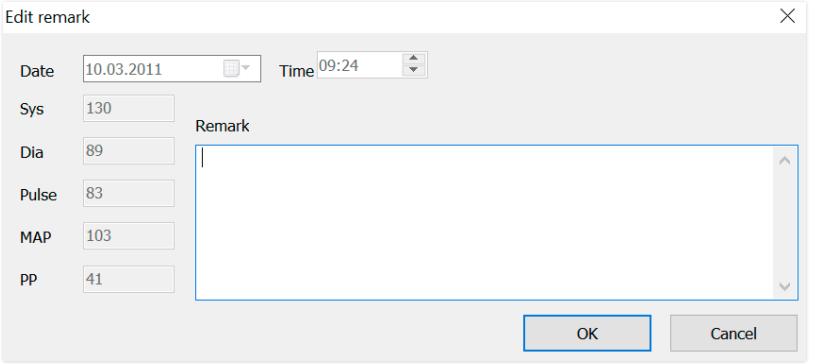


	Date	SYS	DIA	PUL	MAP	PP	\...	Exclude	S	°C	hPa	Osc.	Remark
1	Do, 10.03.2011 - 09:24	130	89	83	103	41		☐					
2	Do, 10.03.2011 - 09:30	150	88	81	109	62		☐					
3	Do, 10.03.2011 - 09:46	121	78	103	92	43		☐					
4	Do, 10.03.2011 - 10:00	117	77	103	90	40		☐					
5	Do, 10.03.2011 - 10:16	120	81	96	94	39		☐					
6	Do, 10.03.2011 - 10:30	115	88	107	97	27		☐					
7	Do, 10.03.2011 - 10:45	112	75	90	87	37		☐					
8	Do, 10.03.2011 - 11:00	132	90	93	104	42		☐					
9	Do, 10.03.2011 - 11:15	131	84	96	100	47		☐					
10	Do, 10.03.2011 - 11:30	124	78	76	93	46		☐					
11	Do, 10.03.2011 - 11:45	124	82	76	96	42		☐					
12	Do, 10.03.2011 - 12:00	123	75	88	91	48		☐					
13	Do, 10.03.2011 - 12:15	146	87	120	107	59		☐					
14	Do, 10.03.2011 - 12:30	138	95	107	109	43		☐					
15	Do, 10.03.2011 - 12:45	127	77	90	94	50		☐					
16	Do, 10.03.2011 - 13:00	126	78	83	94	48		☐					

1 2 3 4 5 6 7 8 9 10 11 12 13 14

The column content is as follows:

1: serial numbers of measurements
2: date and time of measurement
3: SYS = systolic blood pressure
4: DIA = diastolic blood pressure
5: PUL = pulse
6: MAP = mean arterial blood pressure, calculated as DIA + 1/3 pulse pressure
7: PP = pulse pressure (SYS – DIA)
8: Arrhythmia
9: Exclude = if you highlight this, the measurement will not be taken into account for assessment in the profile and statistics
10: S = measurement performed at night
11: Temperature in C°
12: Relative air pressure in hPa
13: Pressure trend during the measurement
14: Remark. Double-click in the measurement line to add a remark to a measurement. This opens the remark input field:



4.2.1 “Delete Period…” button

This irrevocably deletes a complete set of readings.

4.2.2 “Remarks…” button

Remark on a complete set of readings.

4.2.3 “Export GDT” button

This generates the GDT export file manually. Only available if the GDT import of the active patient has already been performed.

4.2.4 “Manual Data…” button

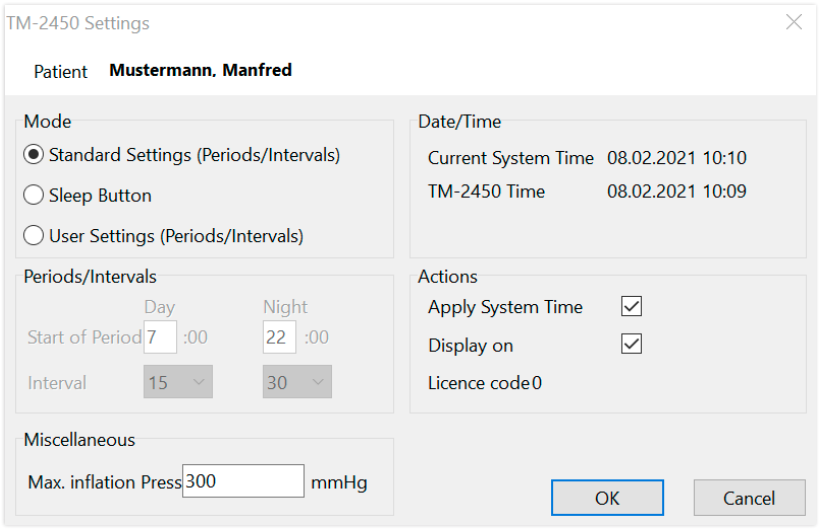
This allows you to add new readings to the active set of readings, or process or delete them.

4.2.5 “Print…” button

This prints out the list of readings.
If you selected “PDF file” in the printer settings (chapter 4.7.3), a PDF file will be created. The name of this PDF file is tm_pat#_YYYYMMDD_m.pdf

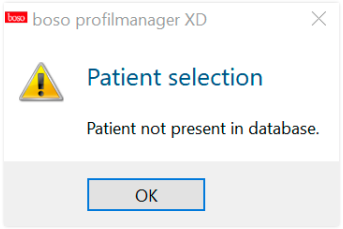
pat# = patient number
YYYYMMDD = date of measurement
m = measurement reference letter

4.2.6 “Programming…” button



The 24-hour measuring device can be initialised with a unique patient number up to 10 characters in length. The benefit of this is that measurements can be immediately assigned to the correct patient when they are read out.

The 24-hour measuring device must be programmed before it is fitted on a patient. Otherwise the following error message will appear when the measurements are read.



You must confirm this error message with “OK” and select the correct patient in the new patient list displayed.

The current patient is automatically transferred to the programming window, and the patient number is assigned to the device (the software generates a numerical identifier, which means that alphanumerical patient numbers can also be used in the boso profil-manager XD).

You can specify a maximum inflation pressure in the “Max. inflation Press.” field. The blood pressure meter will then not inflate beyond the figure you have set here.

If the patient’s systolic blood pressure is close to or above this figure, it will not be possible to measure blood pressure. The device then produces an error message.

The patient number programming and pressure restriction features are not available on TM-2430 devices with serial numbers below SN M 0713550.

Three different modes can be programmed.

Standard Settings (Periods/Intervals)
When this mode is selected, the device takes a reading every 15 minutes between 7 a.m. and 10 p.m., and every 30 minutes between 10 p.m. and 7 a.m.

Sleep Button
In this mode the patient can decide when the night and day intervals should begin, by pressing the AUTO button on the 24-hour measuring device. The benefit of this programming feature is that it allows measurement intervals to be tailored to the patient. For example, for patients with irregular sleep patterns. The interval durations are 15 minutes (day interval) and 30 minutes (night interval).

User Settings (Periods/Intervals)
Two intervals and periods can be programmed according to individual preference in this mode. The interval duration can be set as 5, 10, 20, 30, 60 or 120 minutes.

Display on

Activating or deactivating this command determines whether or not the reading is displayed after the measurement has been performed.

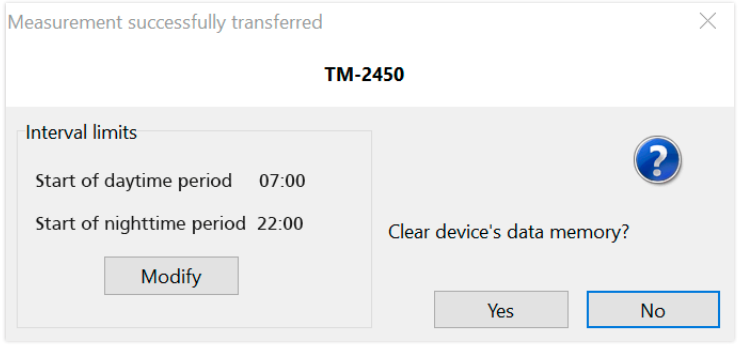
Apply System Time

Activating this command transfers the date and time settings on your PC.Connect the measuring device to the PC connection cable before activating the "Readout Measured Data" button. The measurements are then transferred from the measuring device which is connected.

4.2.7 "Readout Measured Data…" button

Once data have been transferred, the interval limits can be adapted individually to the patient's actual daily routine by clicking the "Modify" button.

Clicking the "Yes" button clears the device's data memory.



4.3 "Sys/dia profile" registry

This displays the blood pressure trend. Move the cursor over the measurement to obtain more information about individual readings. The date, time and reading are displayed in the top left-hand corner of the diagram.
A zoom function is available to display areas of the curve in more detail. To select the zoom area, press the left mouse button and drag the mouse within the diagram from the bottom left-hand corner to the top right-hand corner. To cancel the zoom function, press the left mouse button and drag the mouse within the diagram from the top right-hand corner to the bottom left-hand corner.

4.3.1 "Modify" button

Interval limits can be adapted individually to the patient's actual daily routine by clicking the "Modify" button.

4.3.2 “Reference chart” selection field

Clicking this reads in data from an additional 24-hour measurement into the current graph, so that the two sets of measurements can be compared directly.

4.3.3 “Time scope” selection field

This allows you to select the period for which measurements are displayed. You have the choice of Auto or Day. “Auto” is the default setting. In this setting, the time scope is scaled from the first measurement to the last.

In the “Day" setting, exactly 24 hours are displayed.

Right-clicking in the diagram allows you to shift the graph horizontally with the mouse.

4.3.4 “Print. . .” button

This produces a print-out of the SYS/DIA profile, pulse profile and statistics.

If you selected “PDF file” in the printer settings (chapter 4.7.3), a PDF file will be created. The name of this PDF file is tm_pat#_YYYYMMDD_sys.pdf

pat# = patient number
YYYYMMDD = date of measurement
sys = SYS/DIA reference letter

4.4 “MAP profile” registry

This displays the trend for the calculated mean arterial blood pressure (MAP = diastole DIA + 1/3 pulse pressure PP).

Move the cursor over the measurement to obtain more information about individual readings. The date, time and reading are displayed in the top left-hand corner of the diagram. A zoom function is available to display areas of the curve in more detail. To select the zoom area, press the left mouse button and drag the mouse within the diagram from the bottom left-hand corner to the top right-hand corner. To cancel the zoom function, press the left mouse button and drag the mouse within the diagram from the top right-hand corner to the bottom left-hand corner.

4.4.1 “Modify” button

Interval limits can be adapted individually to the patient's actual daily routine by clicking the "Modify" button.

4.4.2 “Reference chart” selection field

Clicking this reads in data from an additional 24-hour measurement into the current graph, so that the two sets of measurements can be compared directly.

4.4.3 “Time scope” selection field

This allows you to select the period for which measurements are displayed. You have the choice of Auto or Day. “Auto” is the default setting. In this setting, the time scope is scaled from the first measurement to the last.

In the "Day" setting, exactly 24 hours are displayed.

Right-clicking in the diagram allows you to shift the graph horizontally with the mouse.

4.4.4 “Print…” button

This produces a print-out of the MAP profile, pulse profile and statistics.

If you selected “PDF file” in the printer settings (chapter 4.7.3), a PDF file will be created. The name of this PDF file is tm_pat#_YYYYMMDD_map.pdf

pat# = patient number
YYYYMMDD = date of measurement
map = MAP reference letter

4.5 “PP profile” registry

This displays the trend for the calculated pulse pressure (PP = SYS – DIA).

Move the cursor over the measurement to obtain more information about individual readings. The date, time and reading are displayed in the top left-hand corner of the diagram. A zoom function is available to display areas of the curve in more detail. To select the zoom area, press the left mouse button and drag the mouse within the diagram from the bottom left-hand corner to the top right-hand corner. To cancel the zoom function, press the left mouse button and drag the mouse within the diagram from the top right-hand corner to the bottom left-hand corner.

4.5.1 “Modify” button

Interval limits can be adapted individually to the patient's actual daily routine by clicking the "Modify" button.

4.5.2 “Reference chart” selection field

Clicking this reads in data from an additional 24-hour measurement into the current graph, so that the two sets of measurements can be compared directly.

4.5.3 “Time scope” selection field

This allows you to select the period for which measurements are displayed. You have the choice of Auto or Day. “Auto” is the default setting. In this setting, the time scope is scaled from the first measurement to the last.

In the "Day" setting, exactly 24 hours are displayed.

Right-clicking in the diagram allows you to shift the graph horizontally with the mouse.

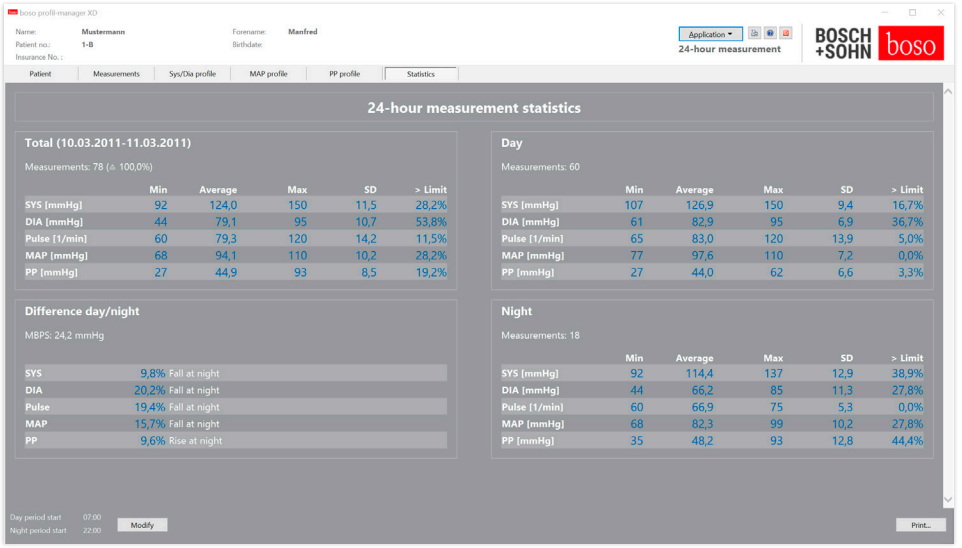
4.5.4 “Print…” button

This produces a print-out of the pulse pressure profile, pulse profile and statistics.

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

pat# = patient number
YYYYMMDD = date of measurement
pp = pulse pressure reference letter

4.6 “Statistics” registry



Measurements for the total period, daytime and nighttime periods are assessed separately. The total value of the readings is displayed in the individual periods. The following values are shown in the individual columns:

Min: smallest value in the interval in question
Average: arithmetic mean in the interval in question
Max: largest value in the interval in question
SD: standard deviation in the interval in question
> Limit: percentage above the limits that have been set
MBPS: morning blood pressure surge
The MBPS indicates the rise in blood pressure after getting up.
MBPS = AvSysDay - AvSysNight

Average Day = average of systolic values in the first two hours of the daytime interval

Average Night = average of the three systolic values surrounding the lowest systolic value in the nighttime interval (one value before the lowest value, the lowest value itself and one value after the lowest value)

The percentage increase/decrease at night is displayed.

4.6.1 "Modify" button

Interval limits can be adapted individually to the patient's actual daily routine by clicking the "Modify" button.

4.6.2 "Print…" button

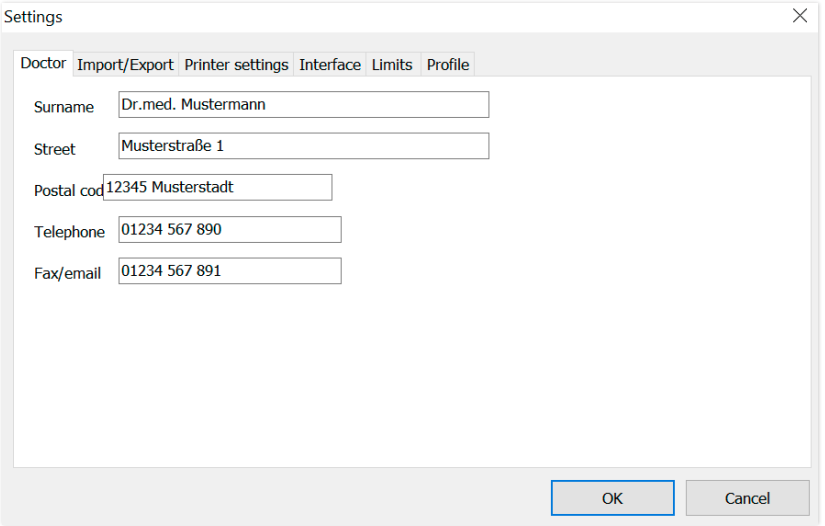
This produces a print-out of the SYS/DIA profile, pulse profile and statistics.

If you selected "PDF file" in the printer settings (chapter 4.7.3), a PDF file will be created. The name of this PDF file is tm_pat#_YYYYMMDD_sys.pdf

pat# = patient number
YYYYMMDD = date of measurement
sys = SYS/DIA reference letter

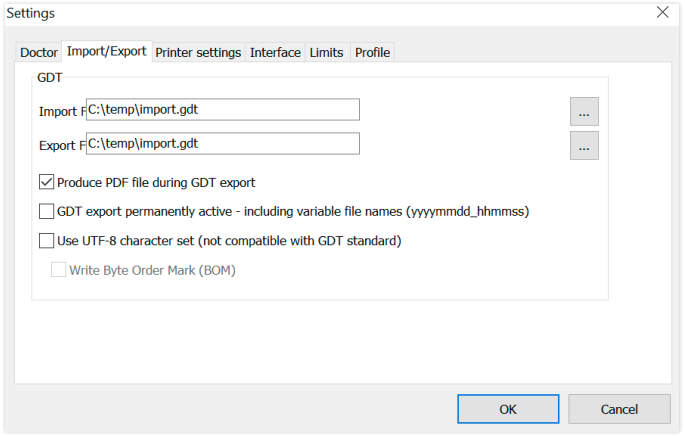
4.7 "Settings…" button in "Patient" registry

4.7.1 "Doctor" sub-registry



The personal details of the doctor treating the patient are entered in the "Doctor" sub-registry and used to produce the footer in the print-out.

4.7.2 “Import/Export” sub-registry



If you are using a clinic data processing system that supports the GDT interface, this is where the path and file names for export and import files are set. You have access to the Windows directory structure via the buttons next to the input fields for import and export files.

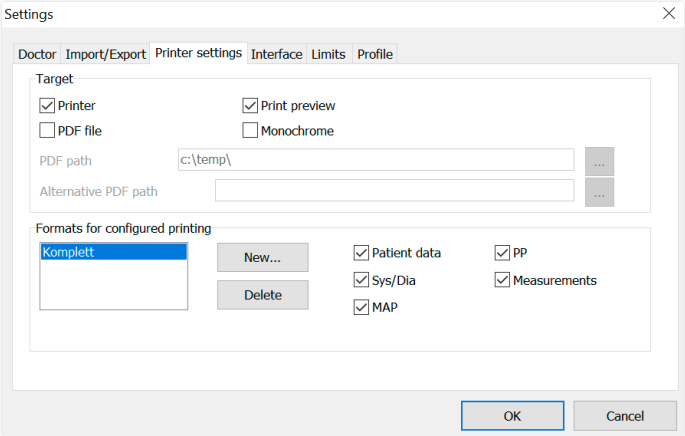
Example: c:\prax_edv\import.gdt
Import file = clinic DP system export file
Export file = clinic DP system import file

GDT import takes place automatically when you start the program, or manually by clicking the “Export/Import -> Import GDT” button if a valid GDT import file is present in the relevant directory. GDT export takes place only if the patient being imported from the clinic DP system is active. Export takes place automatically when the program is closed down (if measurements have been read in from the device during the current program session) or can be performed manually at any time by clicking the "Export GDT" button in the "Measurements" registry.

Data export is deactivated if another patient has been selected after automatic import. It is reactivated when this patient is reselected. Data export is also deactivated if no import has first taken place.

See 3.4.2 for more information about the options available “Produce PDF file during GDT export”, “GDT export permanently active” and “Use UTF-8 character set”.

4.7.3 “Printer settings” sub-registry



In the “Printer settings” registry you decide whether the print-out should be produced in paper form, as a screen print and/or as a PDF document, once the relevant [Print…] buttons have been clicked while the program is running.

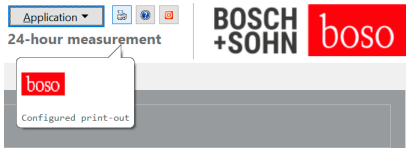
If you select “Printer”, then the Windows print dialogue appears when you click on the [Print…] buttons while the program is running.

If you also select “Print preview” the print preview is displayed before printing.

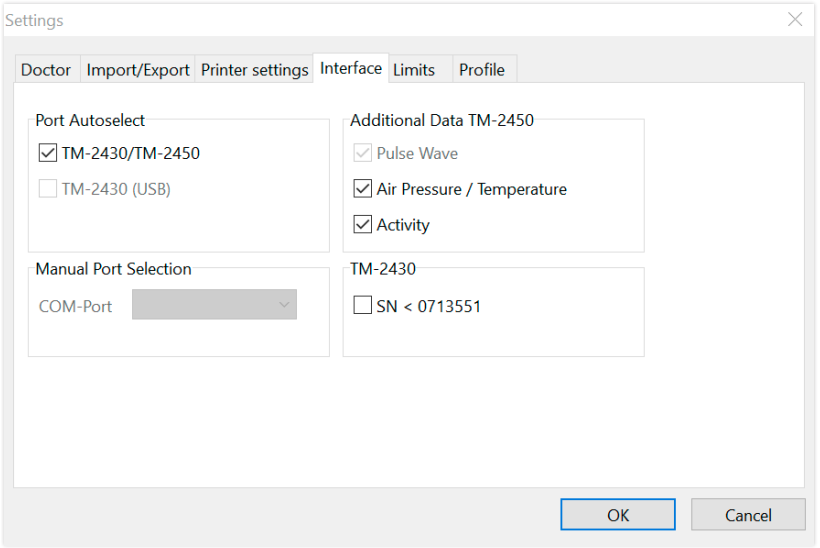
If you select “PDF file”, a PDF file will be created. The name of this PDF file is constructed for the specific application in question, and is described in more detail in the individual applications.

You must select at least one medium “Printer” or “PDF file”.

If you select the “Monochrome” option, the print will be in black and white. If you press the “Configured print-out” printer symbol, the print-out format configured here will be used and only the pages selected here will be printed.



4.7.4 “Interface” sub-registry



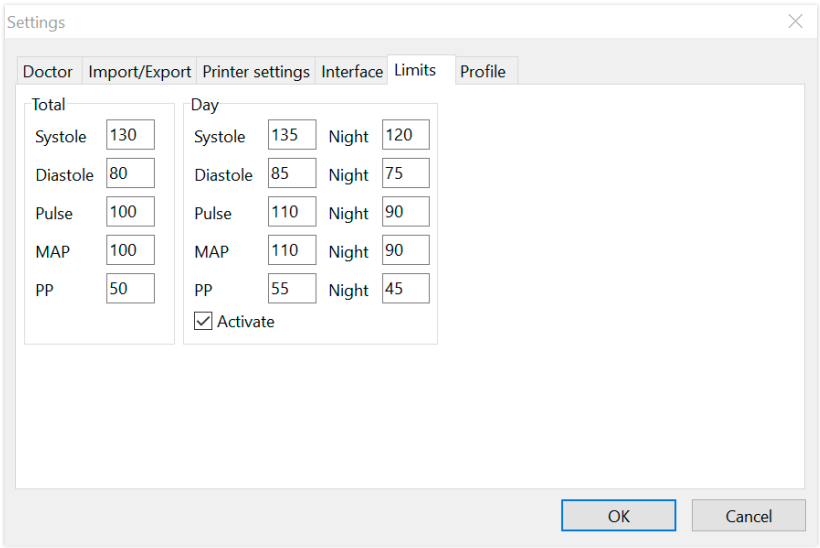
This is where you determine how the connection between the 24h measuring device and the PC is established.

If the “Automatic USB selection” is active, the software always checks which USB port a 24h measuring device is connected to before data transfer. If more than one device is connected at the same time, please disconnect all devices apart from the one that you want to use. You will see a warning telling you to do this.

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

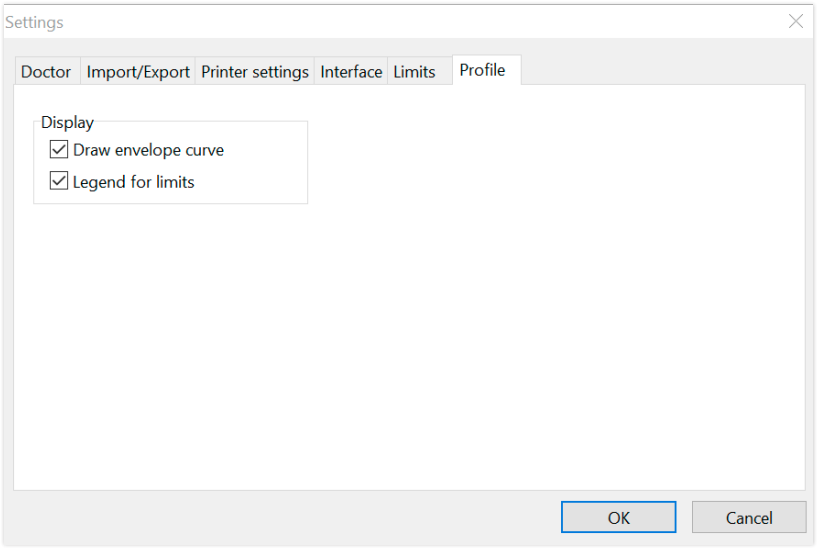
Older models have a more limited set of instructions (no programmable patient number or maximum inflation pressure). Select the appropriate option for TM-2430 devices with serial numbers below SN M0713551.

4.7.5 “Limits” sub-registry



The limits for the individual periods can be set in order to allow customised assessment. The day and night limit settings relate to the interval periods that have been set.

4.7.6 “Profile” sub-registry



In the profile displays (“Sys/Dia, MAP, PP profile” registry), an envelope curve (line connecting the individual measurements) is normally drawn, with the limits shown as horizontal lines.

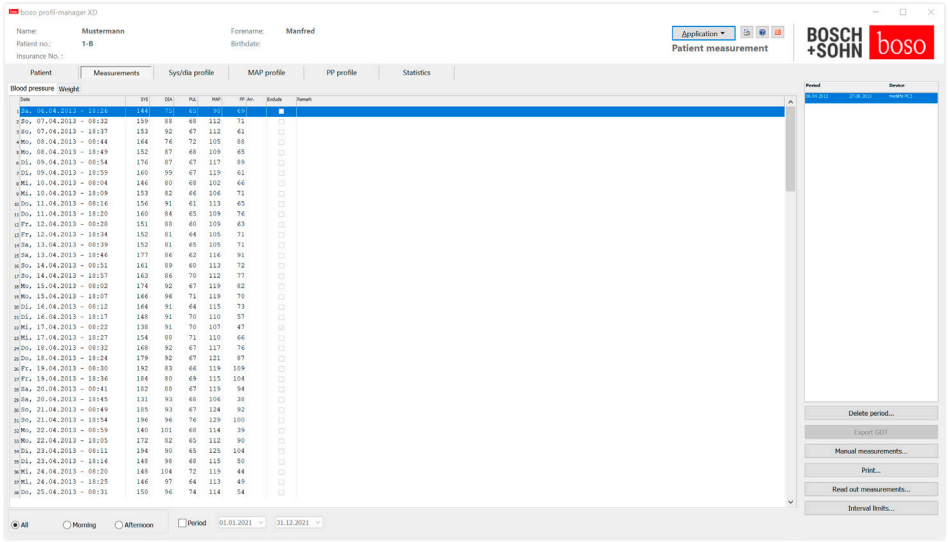
Both the envelope curve and the limit lines can be hidden.

5 “Patient measurement” application

5.1 “Patient” registry

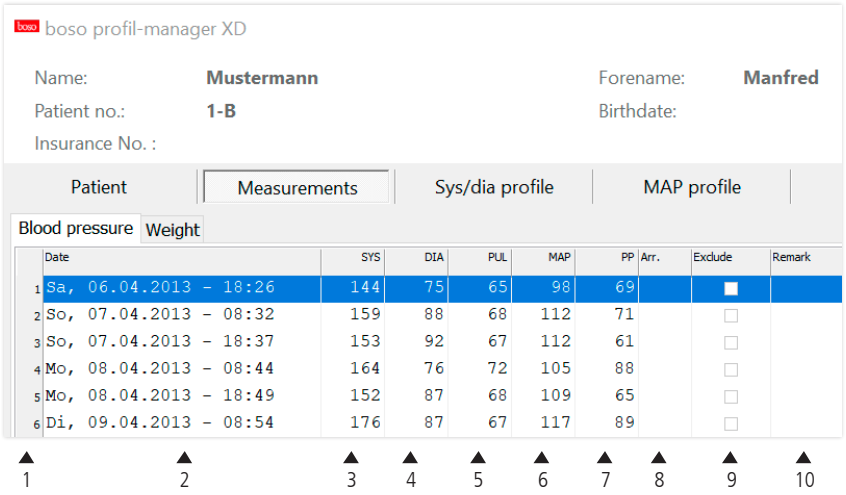
See section “2.1 Patient registry, for all applications”; for “Settings” button, see chapter 5.7.

5.2 “Measurements” registry



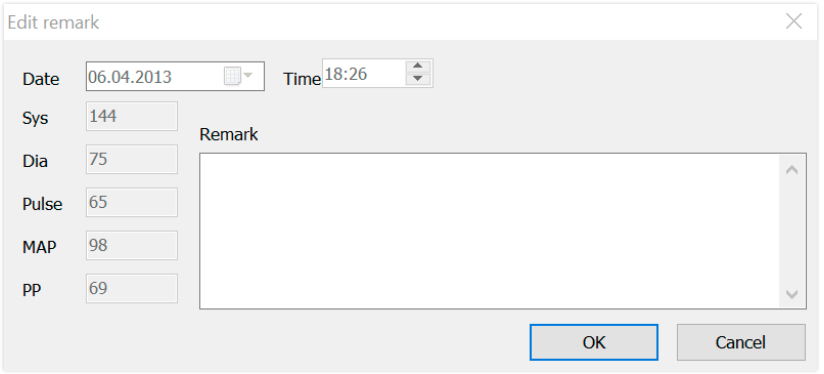
In “Blood pressure” all blood pressure measurements that have been read in to date for the selected patient are displayed. Both the period and the blood pressure meter with which the series of measurements was carried out are displayed.

In “Weight” all weight values transferred from the boso app are displayed.



The column content is as follows:

1: serial numbers of measurements
2: date and time of measurement
3: SYS = systolic blood pressure
4: DIA = diastolic blood pressure
5: PUL = pulse
6: MAP = mean arterial blood pressure (from DIA + 1/3 pulse pressure)
7: PP = pulse pressure (SYS – DIA)
8: Arr. = indication of arrhythmia
9: Exclude = if you highlight this, the measurement will not be taken into account for assessment in the profile and statistics
10: Remark. Double-click in the measurement line to add a remark to a measurement. This opens the remark input field:



5.2.1 “Delete period…” button

This irrevocably deletes a complete set of readings.

5.2.2 “Export GDT” button

This generates the GDT export file manually. Only available if the GDT import of the active patient has already been performed.

5.2.3 “Manual measurements…” button

Additional readings can be added to the active set of readings here.

5.2.4 “Print…” button

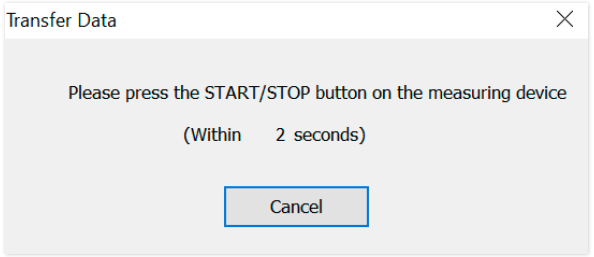
This prints out the list of readings.

If you selected “PDF file” in the printer settings (chapter 5.7.3), a PDF file will be created. The name of this PDF file is medi_pat#_YYYYMMDD_m.pdf

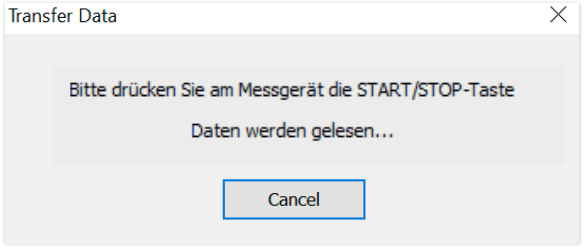
pat# = patient number
YYYYMMDD = date of measurement
m = measurement reference letter

5.2.5 “Read out measurements…” button

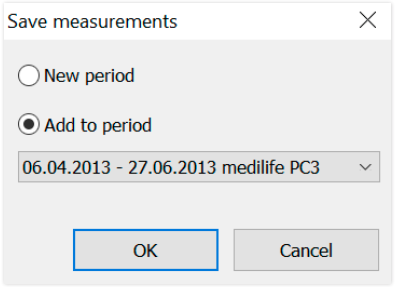
Only for medicus PC2 and medilife PC3.
Connect the measuring device to the PC.



Once you have clicked on the "Read out measurements" button, the START/STOP button on the blood pressure meter must be pressed within 6 seconds in order to transfer data from the blood pressure meter. The measurements are transferred from the measuring device which is connected.



Once data have been successfully transferred, you can set up a new period or assign the data to an existing period.



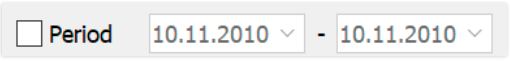
5.2.6 “Interval limits…” button

The limits for morning and afternoon measurements can be defined here. The default setting is midnight to 11:59 a.m. for morning and noon to 11:59 p.m. for afternoon.

5.2.7 “All, Morning, Afternoon” selection

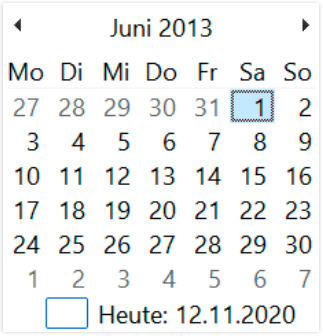
You can restrict the reading selection to only morning measurements or only afternoon measurements here.

5.2.8 “Period” selection



You can select a specific period for assessment among all the readings by selecting a period.

Click on the arrow symbol in the data fields to open a calendar, making selection easier.



Click on the month or year to change it immediately.

5.3 “Sys/dia profile” registry

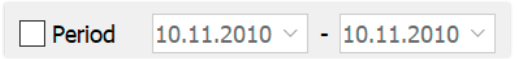
This displays the blood pressure trend.

Move the cursor over the measurement to obtain more information about individual readings. The date, time and reading are displayed in the top left-hand corner of the diagram. A zoom function is available to display areas of the curve in more detail. To select the zoom area, press the left mouse button and drag the mouse within the diagram from the bottom left-hand corner to the top right-hand corner. To cancel the zoom function, press the left mouse button and drag the mouse within the diagram from the top right-hand corner to the bottom left-hand corner.

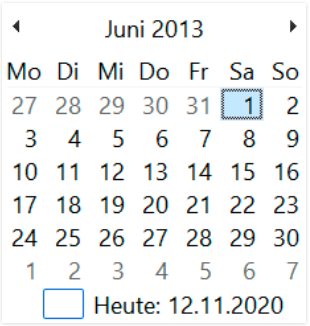
5.3.1 “All, Morning, Afternoon” selection

You can restrict the reading selection to only morning measurements or only afternoon measurements here.

5.3.2 “Period” selection



You can select a specific period for assessment among all the readings by selecting a period. Click on the arrow symbol in the data fields to open a calendar, making selection easier. Click on the month or year to change it immediately.



5.3.3 “Time scope” selection field

This allows you to select the period for which measurements are displayed. You have the choice of Auto, Day, Week, Month, Quarter or Year.
“Auto” is the default setting. In this setting, the time scope is scaled from the first measurement to the last.
Right-clicking in the diagram allows you to shift the graph horizontally with the mouse.

5.3.4 “Print...” button

This produces a print-out of the SYS/DIA profile, pulse profile and statistics.

If you selected “PDF file” in the printer settings (chapter 5.7.3), a PDF file will be created. The name of this PDF file is medi_pat#_YYYYMMDD_sys.pdf

pat# = patient number
YYYYMMDD = date of measurement
sys = SYS/DIA reference letter

5.4 “MAP profile” registry

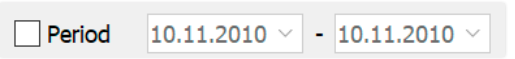
This displays the trend for the calculated mean arterial blood pressure (MAP = diastole DIA + 1/3 pulse pressure PP).

Move the cursor over the measurement to obtain more information about individual readings. The date, time and reading are displayed in the top left-hand corner of the diagram. A zoom function is available to display areas of the curve in more detail. To select the zoom area, press the left mouse button and drag the mouse within the diagram from the bottom left-hand corner to the top right-hand corner. To cancel the zoom function, press the left mouse button and drag the mouse within the diagram from the top right-hand corner to the bottom left-hand corner.

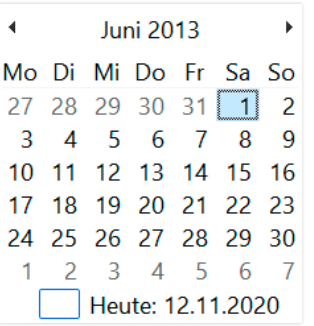
5.4.1 “All, Morning, Afternoon” selection

You can restrict the reading selection to only morning measurements or only afternoon measurements here.

5.4.2 “Period” selection



You can select a specific period for assessment among all the readings by selecting a period. Click on the arrow symbol in the data fields to open a calendar, making selection easier. Click on the month or year to change it immediately.



5.4.3 “Time scope” selection field

This allows you to select the period for which measurements are displayed. You have the choice of Auto, Day, Week, Month, Quarter or Year.

“Auto” is the default setting. In this setting, the time scope is scaled from the first measurement to the last.

Right-clicking in the diagram allows you to shift the graph horizontally with the mouse.

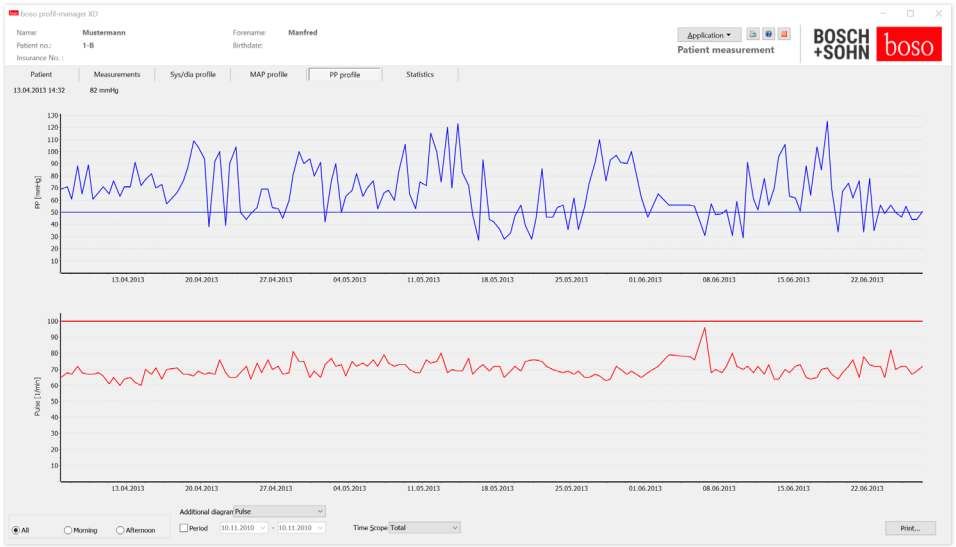
5.4.4 “Print...” button

This produces a print-out of the MAP profile, pulse profile and statistics.

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

pat# = patient number
YYYYMMDD = date of measurement
map = MAP reference letter

5.5 “PP profile” registry



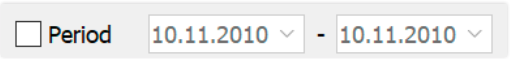
This displays the trend for the calculated pulse pressure (PP = SYS – DIA).

Move the cursor over the measurement to obtain more information about individual readings. The date, time and reading are displayed in the top left-hand corner of the diagram. A zoom function is available to display areas of the curve in more detail. To select the zoom area, press the left mouse button and drag the mouse within the diagram from the bottom left-hand corner to the top right-hand corner. To cancel the zoom function, press the left mouse button and drag the mouse within the diagram from the top right-hand corner to the bottom left-hand corner.

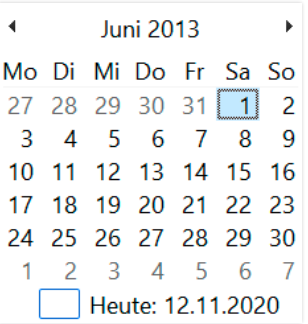
5.5.1 “All, Morning, Afternoon” selection

You can restrict the reading selection to only morning measurements or only afternoon measurements here.

5.5.2 “Period” selection



You can select a specific period for assessment among all the readings by selecting a period. Click on the arrow symbol in the data fields to open a calendar, making selection easier. Click on the month or year to change it immediately.



5.5.3 “Time scope” selection field

This allows you to select the period for which measurements are displayed. You have the choice of Auto, Day, Week, Month, Quarter or Year.

“Auto” is the default setting. In this setting, the time scope is scaled from the first measurement to the last.

Right-clicking in the diagram allows you to shift the graph horizontally with the mouse.

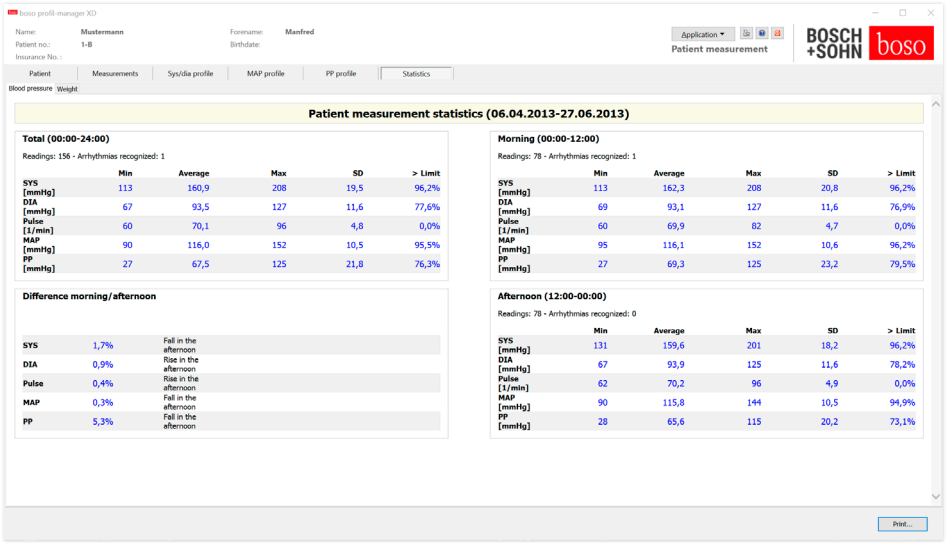
5.5.4 “Print. . .” button

This produces a print-out of the pulse pressure profile, pulse profile and statistics.

If you selected “PDF file ” in the printer settings (chapter 5.7.3), a PDF file will be created. The name of this PDF file is medi_pat#_YYYYMMDD_pp.pdf

pat# = patient number
YYYYMMDD = date of measurement
pp = pulse pressure reference letter

5.6 “Statistics” registry



Measurements for the complete period, morning and afternoon periods are assessed separately.

The total number of readings in the individual periods, and the number of arrhythmias recognised, are displayed.

The following values are displayed in the individual columns:

Min: smallest value in the interval in question

Average: arithmetic mean in the interval in question

Max: largest value in the interval in question

SD: standard deviation in the interval in question

> Limit: percentage above the limits that have been set. The percentage increase/decrease in the afternoon is displayed.

5.6.1 “Print...” button

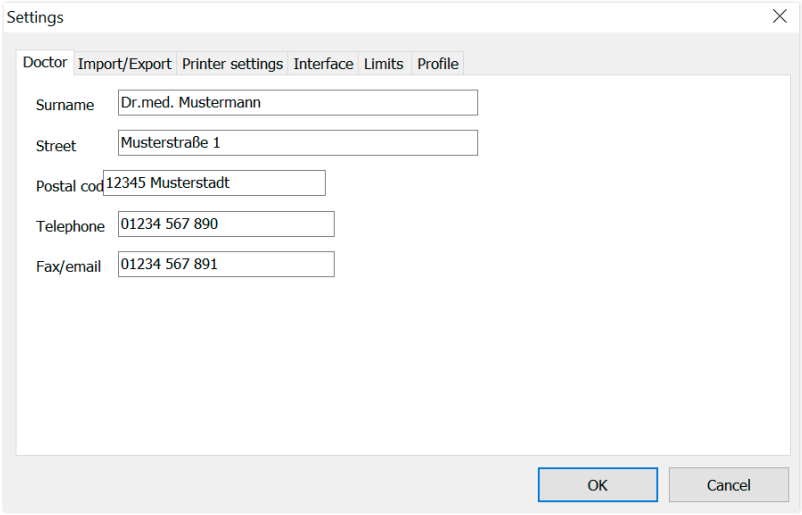
This produces a print-out of the SYS/DIA profile, pulse profile and statistics.

If you selected “PDF file” in the printer settings (chapter 5.7.3), a PDF file will be created. The name of this PDF file is medi_pat#_YYYYMMDD_sys.pdf

pat# = patient number
YYYYMMDD = date of measurement
sys = SYS/DIA reference letter

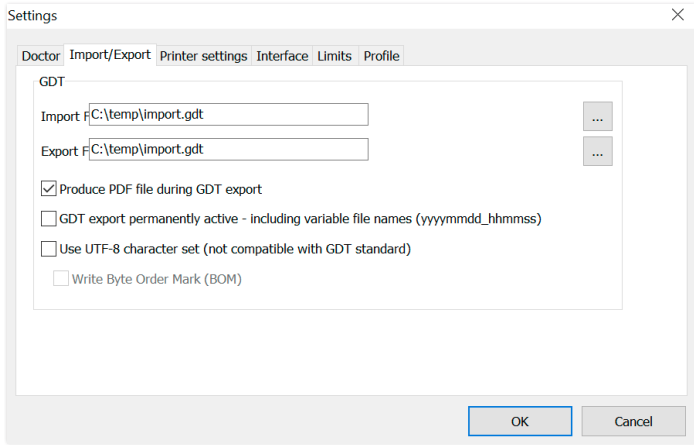
5.7 “Settings…” button in “Patient” registry

5.7.1 “Doctor” sub-registry



The personal details of the doctor treating the patient are entered in the “Doctor” sub-registry and used to produce the footer in the print-out.

5.7.2 “Import/Export” sub-registry



If you are using a clinic data processing system that supports the GDT interface, this is where the path and file names for export and import files are set. You have direct access to the Windows directory structure via the buttons next to the input fields for import and export files.

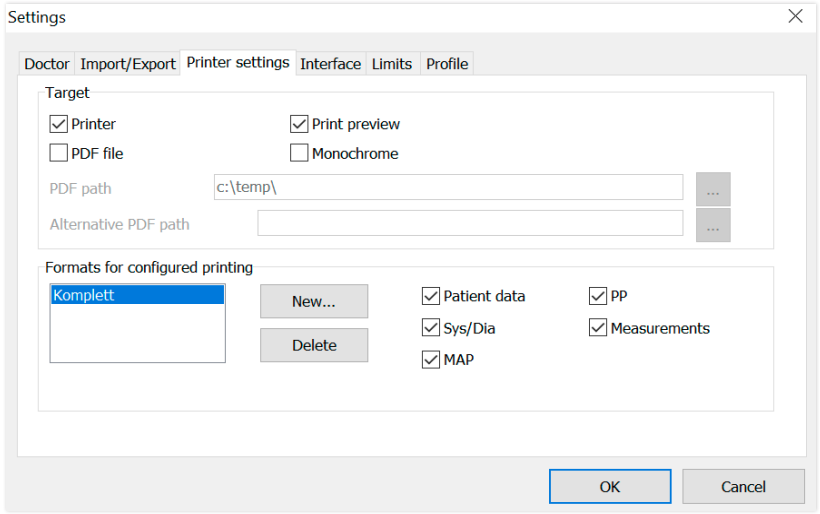
Example: c:\prax_edv\import.gdt
Import file = clinic DP system export file
Export file = clinic DP system import file

GDT import takes place automatically when you start the program, or manually by clicking the “Export/Import -> Import GDT” button if a valid GDT import file is present in the relevant directory. GDT export takes place only if the patient being imported from the clinic DP system is active. Export takes place automatically when the program is closed down (if measurements have been read in from the device during the current program session) or can be performed manually at any time by clicking the "Export GDT" button in the "Measurements" registry.

Data export is deactivated if another patient has been selected after automatic import. It is reactivated when this patient is reselected. Data export is also deactivated if no import has first taken place.

See 3.4.2 for more information about the options available “Produce PDF file during GDT export”, “GDT export permanently active” and “Use UTF-8 character set”.

5.7.3 “Printer settings” sub-registry



In the “Printer settings” registry you decide whether the print-out should be produced in paper form, as a screen print and/or as a PDF document, once the relevant [Print…] buttons have been clicked while the program is running.

If you select “Printer”, then the Windows print dialogue appears when you click on the [Print...] buttons while the program is running.

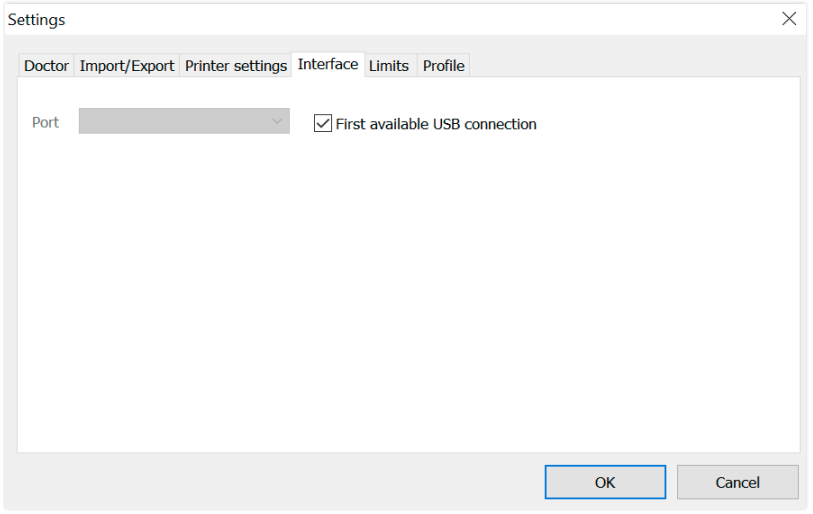
If you also select “Print preview”, the print preview is displayed before printing.

If you select “PDF file”, a PDF file will be created. The name of this PDF file is constructed for the specific application in question, and is described in more detail in the individual applications.

You must select at least one medium: “Printer” or “PDF file”.

If you select the “Monochrome” option, the print will be in black and white. If you press the “Configured print-out” printer symbol, the print-out format configured here will be used and only the pages selected here will be printed.

5.7.4 “Interface” sub-registry

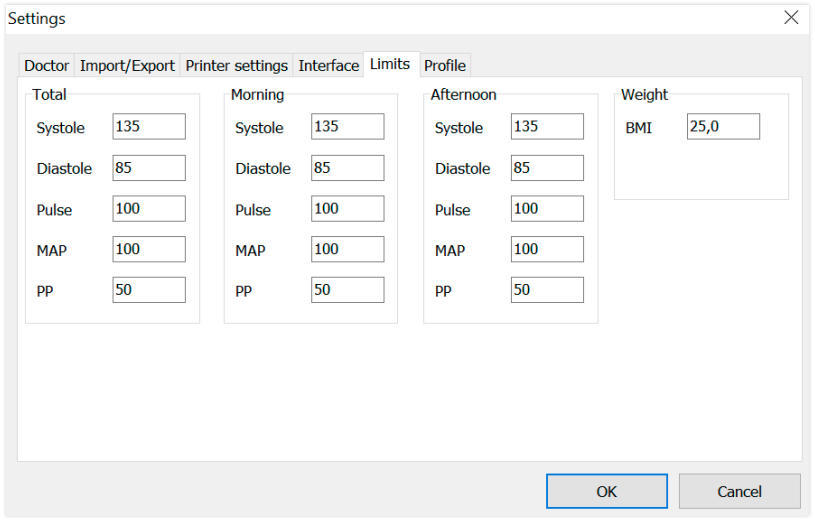


This is where you determine how the connection between the blood pressure meter and the PC is established.

If the “First available USB connection” option is active, the first FTDI USB port under Windows will be used to transfer data. If more than one FTDI USB port is installed, disconnect the ports that are not needed from the computer, or deactivate the option.

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

5.7.5 “Limits” sub-registry

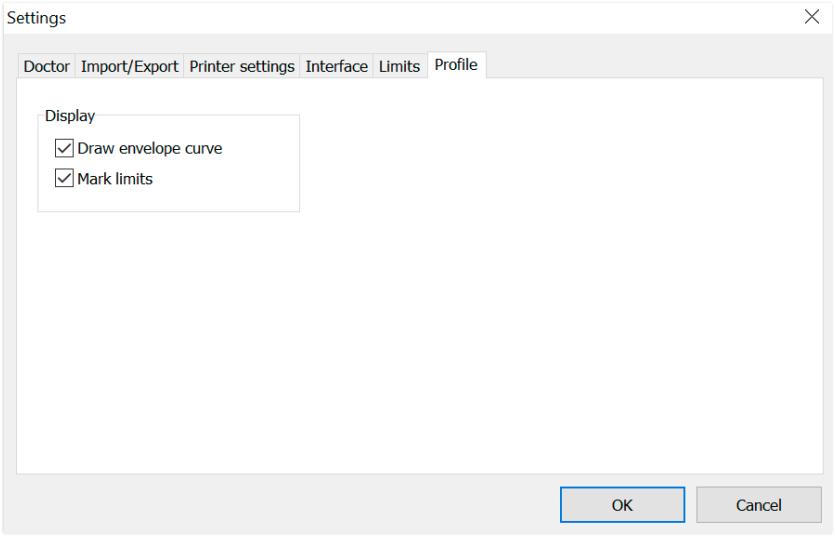


The limits for the individual periods can be set in order to allow customised assessment. The limit settings for morning and afternoon are based on the morning and afternoon interval periods.

5.7.6 “Profile” sub-registry

In the profile displays (“Sys/Dia, MAP, PP profile” registry), an envelope curve (line connecting the individual measurements) is normally drawn, with the limits shown as a horizontal line.

Both the envelope curve and the limit lines can be hidden.



6 Warranty provisions

Irrespective of statutory warranty rights, boso guarantees the software data carrier to be free from material and processing defects for 90 days from the date of purchase.

In the light of the warranty undertaking given above, boso is obliged to replace the data carrier and the software it contains under the following conditions:

- the customer/purchaser notifies boso of the defect in writing within 90 days of the date of purchase

or

the customer/purchaser returns the defective data carrier to the dealer, or directly to boso at the address below, within 90 days:

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

boso does not offer any warranty, either explicitly or tacitly, beyond the warranty undertaking given above.

7 Limitation of liability

a) The software is supplied to you on the basis of the current state of development.

b) Irrespective of the provision set out in chapter 6, boso and its dealers accept no liability for risks with regard to the results and performance of the software. We bear no liability for indirect losses, consequential losses, loss of earnings, losses due to lost or damaged data or other commercial or financial losses.

c) The aforementioned exclusion of liability does not apply to liability under product liability legislation or to cases of deliberate action or gross negligence on our part or on the part of our agents.

8 Explanation of symbols

Read the user manual

Year of manufacture

Manufacturer

CE 0124

The CE mark documents compliance with the Medical Devices Directive 93/42/EEC, Notified Body: DEKRA, 0124

Important information

MD

Medical device

Extract from GDT record description

The record types and their field identifiers needed to create the GDT interface of this software are described below:

Record type 6302 “Request new examination”

Field 8000:	record identification
8100:	record length
8315:	GDT ID of recipient
8316:	GDT ID of sender
8410:Testident	(BDM00: Shortcut patient measurement
	BDM01: Shortcut 24-hour measurement
	BDM02: Shortcut ABI/PWV measurement)
9218:	GDT version number
3000:	patient number
3101:	patient’s surname
3102:	patient’s first name
3103:	patient’s date of birth
3105:	insurance number
3106:	patient's address (town)
3107:	patient’s address (street)
3110:	patient’s gender (1 = male, 2 = female)
3622:	patient’s height (cm)
3623:	patient’s weight (kg)

Record type 6310 “Transmit data from examination”

Field 8000:	record identification
8100:	record length
8315:	GDT ID of recipient
8316:	GDT ID of sender
9218:	GDT version number
3000:	patient number/patient identification
8402:	map for a particular device and process
6200:	date of examination
6228:	results table text, formatted
6302:	file archiving identifier
6303:	file format
6304:	file content
6305:	file reference

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Subject to errors and alterations | 02/2021

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