enverdis®

MEDICAL SOLUTIONS

VASCULAR EXPLORER

ABI+AIx SOFTWARE

OPERATOR'S MANUAL

Version 2.5   09/2012

INDEX

1 PREFACE

Dear Customer,

This operator's manual is intended for users of the "ABI+AIx" module, designed for the VASCULAR EXPLORER product family. Hereinafter, this module will be referred to as the ABI+AIx software.

This manual describes the setup and operation for this module. The sections are set up to teach the user how to use the software step-by-step and with a short learning curve.

The VASCULAR EXPLORER ABI+AIx software module lets you perform plethysmographic vascular analysis to detect arteriosclerosis and diabetic macro- and microangiopathies. Photoplethysmographic sensors attached to the patient's fingers and toes provide a quick overview of all major upstream arterial vessels and regional arterial capillaries. The ABI+AIx module can also be used to determine the arterial status based on the parameters ankle-brachial index (ABI), augmentation index (AIx) and pulse wave velocity (PWV).
Intelligent algorithms help you interpret findings by taking automatic measurements, presenting the parameters with their normal ranges and suggesting a diagnosis.

Please read through this operator's manual carefully before you use the software.

The installation procedure is described in the section "Installation and deinstallation" of the respective manual for the "VASCULAR EXPLORER – CORE SYSTEM". If you have any questions concerning this product or our services, please feel free to contact us at any time.

Copying (even of excerpts) and reproduction of this operator's manual are not permitted.

The operator's manual constitutes a part of the device and should therefore always be kept in the direct vicinity of the device.

1.1 Important notes

Important notes on special labeling

This operator's manual contains important notes concerning the protection of the program and alternative options for using the equipment that are highlighted as follows:

NOTE!   This offers an alternative way to use the program most effectively or gives important information.

Terms governing use of the software

enverdis GmbH reserves all rights to the software including the right of duplication, distribution and translation.

The right to utilization may not be transferred to any third parties without the express written permission of enverdis GmbH.

Notes on the figures used

All names used in the examples and figures have been invented. Any resemblance to real persons is purely coincidental. The data are fictitious and have no basis in fact.

Liability disclaimer

enverdis GmbH is not liable for unprofessional or improper use of this ABI+AIx software.

The manufacturer reserves the right to make revisions or modifications to the software at any time and without prior notice.

1.2   System requirements

	Minimal requirements:
CPU:	Intel i3
RAM:	3 GB
Graphic:	Intel HD
Display:	15 inches with 1270x800 pixel resolution
Ports:	2 x USB 2.0
Operating system:	Windows XP

NOTE!   In any case you must use a power supply with protective earthing conductor.

NOTE!   If your system doesn't meet the minimal requirements there may be certain restrictions in usability and loss of data.

2   PERFORMANCE FEATURES

- 2-channel recording of the photoplethysmogram

- 2-channel blood pressure recording

- Presentation, measurements
    - Editable plots of ABI and AIx
    - Display of the representative beats as AIx

- Interpretation
    - Automatic detection of closing pressures for the ABI
    - Automatic detection of points P0, P1, P2 and ED in the AIx
    - Calculating the PWV in the AIx

- Additional function
    - Exporting the findings as a Microsoft Excel (XLS) file

- Print manager
    - Printing manually selected views
    - Print preview via screenshots
    - PDF printouts via additional software

3   OPERATION

In the following sections, you will find explanations about the methods for operating the ABI+AIx software and descriptions about the functionality of each of the individual screen elements. You will learn how to start an ABI, AIx and ABI+AIx examination and perform the analysis after the examination.

Important notes

- Before you start a recording, you must select a patient from the patient data management PATIENT EXPLORER or register a new patient.
- All automatic findings and important notes on the ABI+AIx software should only be regarded as proposals made by the software in the sense of a "second opinion".
- When rendering a diagnosis, it is paramount that a qualified physician review and evaluate the results.

3.1   General explanations on the user interface / presentation

Your monitor must support a resolution of at least 1024 x 768 pixels. Lower resolutions will result in a poor display and are therefore not recommended.

The illustration below (Fig. 1) shows the basic structure of the recording screen:
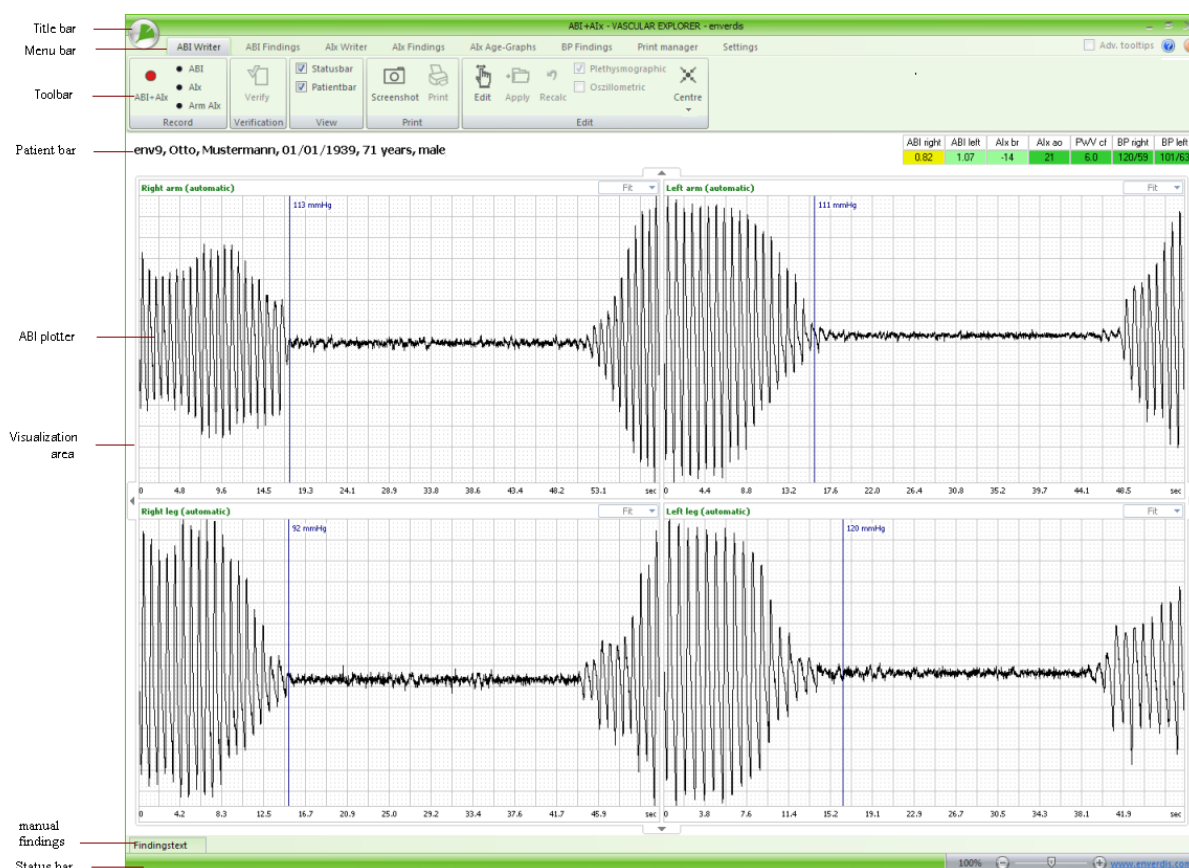

Fig. 1: Software module screen

4 SCREEN BARS

The next sections explain the basic content of the individual screen bars used in the ABI+AIx software.

Toolbar

The individual buttons for operating the ABI+AIx software are arranged in the toolbar. The buttons are divided into groups of icons (e.g. "View"). The individual buttons are explained in the table in Section DESCRIPTION OF BUTTON FUNCTIONS. The contents of the toolbar depend on the tab selected.

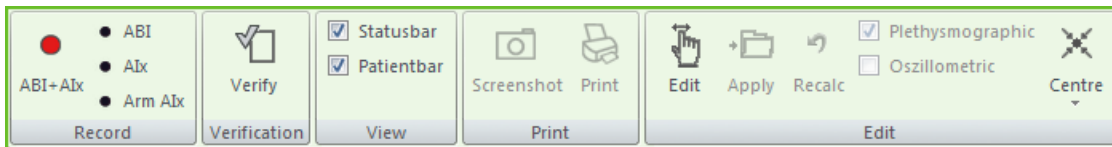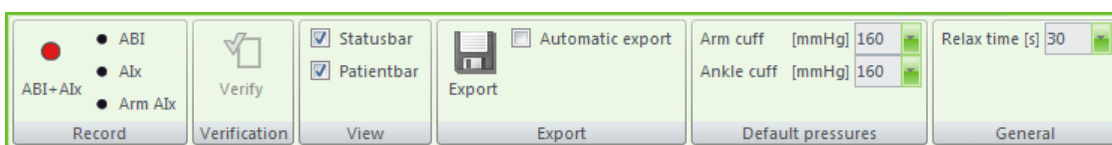*Fig. 2: Toolbar – ABI Writer*

Fig. 3: Toolbar – Settings

Information bar

Patient data are displayed on the left side of the information bar. The age represents the age at the time of recording. Use the context menu (activated by hovering the mouse over the information bar and clicking on the right mouse button) to deselect or toggle to individual display elements. On the right side, the following values are displayed as a function of examination type: ABI, right; ABI, left; brachial AIx; Aortic AIx; PWV cf; blood pressure, right; Blood pressure, left. You can also toggle back and forth between these values. Missing descriptive values and incalculable parameters are indicated by "---".

Fig. 4: Information bar

Status bar

In the far outer right, you will find the link to the enverdis website. To the left, you will find the zoom slider for the findings report. Use the slider to increase or decrease the font size.

Fig. 5: Status bar

4.1 Title bar

The title bar depicts the enverdis logo on the left side and in the middle the software name. On the right side, you will find the standard Windows symbols for maximizing, minimizing and closing windows.

Click on the enverdis symbol [image] to open the "Patient card". This contains top right of the title the type of examination ("ABI+AIx", "ABI", "AIx" or "Arm AIx"). The entries below include the patient's ID (generated by PATIENT EXPLORER), patient's first name and last name, their date of birth and age, gender, height and weight. Additionally, the date and time of the examination and its status are displayed. Examinations can have the following status: Editable, No recording possible, Blocked, Verified by User name on Date.

The button in the lower right is for exiting the software module.

Additional buttons are located on the left-hand side.
Press "Help" to open the operator's manual. If no manual is available, this button will not be displayed.
Press "About" to open a box containing the version of your software and contact information.
Press "Log file" to gather support information.

4.2   Menu bar

The menu bar contains the tabs "ABI Writer", "ABI Findings", "AIx Writer", "AIX Findings", "AIx Age graph", "BP findings", "Print manager" and "Settings", all of which will be explained in greater detail in the following sections.
On the right-hand margin, there are additional buttons for "Help" ("?") and "About" ("i").
Use the first button to open the operator's manual and the second to get the version of your software and contact information.
If no operator's manual is available, the Help button is hidden.
You can additionally activate the advanced tooltips menu for more detailed hints about particular control elements.

All toolbar elements have the same basic structure, but are displayed as a function of the tab selected. By clicking any of these tabs, you can start a recording or verify an existing recording as long as you have been assigned the corresponding rights.
In addition, you can toggle between the status and information bar (see . SCREEN BARS) or create and print out a screenshot of the current view (see PRINT).

4.2.1   Settings

For general settings, click "Settings" to activate the toolbar. The last view will still remain visible in the view area.
With this tab, you can enter the basic settings for the examination.

Here you can set the duration of the recovery phase and the target pressures for the arm and ankle cuffs in mmHg.
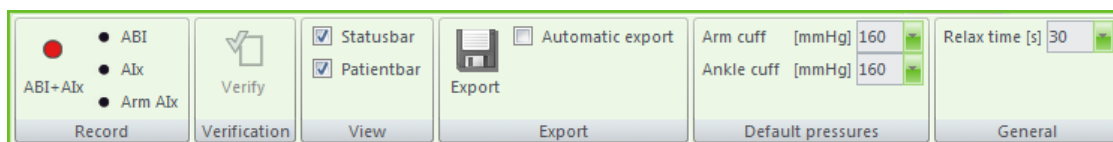

Fig. 6: Settings

NOTE!   When selecting target pressures for both arms and ankles avoid values too low since repeated pumping will affect the duration of the measurement as well as values too high which could cause pain for the patient.

When performing an ABI measurement, you can freely select the target pressures (see Target pressures).
When an AIx measurement is carried out, the blood pressure must be measured first to determine the diastolic and suprasystolic pressure levels. You can likewise freely choose the cuff pressure for this blood pressure measurement.

Furthermore, you can also set the duration of the recovery phase between two recordings in order to allow the physiological processes in the vessels to regenerate themselves.

If a export license available it is possible to export measured data of a successful ended recording. To activate automatic export after each recording check the box "Automatic export".

NOTE!   Your preferred settings have been saved. These should only be changed when necessary.

5 DESCRIPTION OF BUTTON FUNCTIONS

The following table describes the functions of the individual buttons.

Toolbar	
	Start recording
	Verifies a finding
	Prints the content of the current display
	Generates a screenshot of the current display for the print manager
	Activate/deactivate the Edit mode
	Apply changes
	Recalculation
	Centers the plethysmographic closing pressures measured or the representative cycle
	Open patient card
Toolbar buttons	

ABI|AIx Writer	
Fit	List for selecting curve presentation size
Previous	Edit mode (AIx Writer) – Move the representative beat to the left
Next	Edit mode (AIx Writer) – Move the representative beat to the right
Buttons for ABI|AIx Writer	

Print manager	
	Saves all selected screenshots
Button for Print manager	

Settings	
	Export specific data as a Microsoft Excel (XLS) file
Button for Settings	

Shortcuts	
Esc	End recording (wizard)
Alt + F4	Exit the module
Strg+V	Insert (manual findings)
Strg+P	Print
Strg+C	Copy (manual findings)
Strg+X	Cut (manual findings)
Strg+Z	Undo (manual findings)
Strg+A	Highlight all (manual findings)
F1	Opens the operator's manual
Description of the shortcuts used by the software	

6 GENERAL PROCEDURES

The following describes the various general functions and procedures featured by the ABI+AIx software.

6.1 Preparing for an examination

Before starting the measurement, the patient should lie down in a room at a comfortable temperature for at least 10 minutes. The patient should remain in a comfortable resting position while the measurement is taken.
To ensure optimal examination conditions, it is essential that the patient not: smoke or use nicotine, eat any food, or drink any alcohol or hot drinks such as coffee or tea, for three hours before the examination.

6.2 Connecting and applying the cuffs

The first step is to fit the cuffs to the patient's upper arm and ankle. Care must be taken that the red arrows attached to the cuffs are located above the brachial artery on the arm and above the posterior tibial artery on the ankle. The lower edge of the arm cuff should be positioned 2.5 cm above the elbow, while the ankle cuff should be positioned with the red arrow pointing towards on the inside of the foot, above the ankle.

NOTE!   The cuffs on both the arm and the ankle should be applied with a moderately tight fit!

The cuffs are available in the sizes "Child", "Normal adult" and "Large adult". To ensure successful results, the cuffs must be fitted to the person to be examined in accordance with their upper arm circumference.

Arm circumference	Cuff size
19 - 29 cm	Child
29 - 40 cm	Standard Adult
38 - 50 cm	Large Adult

NOTE!   On the ankle, always use cuffs without clips, as the clips may press on the arteries, thereby falsifying the measuring results!

NOTE!   Care must be taken that the cuff pipe can move freely and is not bent!

- The patient should not move, speak or cough during the recording as this may result in malfunctions that could falsify the findings.

6.3 Connecting and applying the SPO2 sensors

The sensor cables (6-lead) are plugged into the Minimed sockets on the back of the VASCULAR EXPLORER. The plugs and sockets are coded so that the plugs can only be inserted into the sockets in one direction. Never use force to make or break this plug connection.

NOTE!   Please only use the sensors supplied with the VASCULAR EXPLORER.

NOTE!   The photoplethysmographic sensors are available in various sizes, so that they can be optimally adapted to all fingers or toes.

Attach the photoplethysmographic sensors to the index finger and the second toe, distally from the cuff:

- Place one of the patient's fingers (preferably the index, middle or ring finger) into the clamping sensor until the tip touches the stop. The fingernail should be turned to the upper side of the sensor. Please ensure that the patient's fingernails are not so long that they adversely affect correct finger positioning. The same technique applies to the toes; preferably use the 2nd toe.
- Ensure that the patient's body temperature is suitable for carrying out photoplethysmographic measurements (good circulation in the extremities).

NOTE!   It is particularly important to prevent the patient's feet from getting too cold. If necessary, cover them with a blanket!

- When attaching the photoplethysmographic sensors, make sure that the sensors are not exposed to direct sunlight. Otherwise, this might falsify the results. If necessary, cover the sensors with a blanket.

Correct sensor positioning is decisive for good results. If the sensor is not positioned properly, light may bypass the tissue and result in inaccurate results.

NOTE!   Never use a damaged sensor.

NOTE!   The sensors may not be autoclaved, sterilised using ethylene oxide or immersed in liquids. Do not use aggressive cleaning agents. Cleaning instructions are included in the operating manual for the "VASCULAR EXPLORER - CORE SYSTEM".

The following conditions may negatively affect the measuring accuracy:

- too bright ambient lighting
- strong movements
- arterial catheters or blood pressure cuffs (unless required for the measuring method)
- moisture in the sensor
- carboxyhemoglobin
- methemoglobin
- artificial finger nails
- poor pulse quality
- too low a temperature of the extremities
- Nail polish
- patients with anemia or low hemoglobin levels

6.4   General functionality

Starting a recording

With the "Record" buttons you can select the following recording modes: "ABI+AIx", "ABI", "AIx" or "Arm AIx". Start a new recording by clicking on the appropriate button. A wizard screen appears to guide you through the recording. You can exit the wizard at any time by pressing the "Cancel" button.
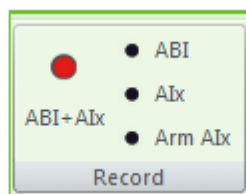

Fig. 7: Select recording mode

Verification

If the current examination is not in Edit mode users with verification rights can verify the current examination or cancel its verification.

The verified finding is thus write-protected and secured against unwanted revision. The findingstext title indicates the date and name of the user who has carried out the verification. That also cancels any editing options. The verification icon is activated.

Clicking the button ![icon] again undoes the verification.

NOTE!   Only qualified physicians should have authorization rights to verify findings. The right to verify a finding is allocated to the respective users in the user administration function of the PATIENT EXPLORER.

Print

Click on the button ![icon] to generate a screenshot of the current display and save it in the print manager.

Click on the button ![icon] to print the current display.

Center

Using ![icon] the center button you display the occlusion pressure positions of the 'ABI Writer' or the representative cycles of the 'AIx Writer' in the center of the screen.

This button provides a context menu with settings for the wave form context. It is similar to those of each wave form (see ABI curves or AIx pressure curves). By selecting an option all views receive the same setting.

6.5   Edit

Edit mode (Edit ![icon])

Switch on the Edit mode by clicking on the edit button ![icon]. This applies to all curves and to all findings from the current examination.

When the Edit function is activated, you have the option to change parameters at your discretion. On an ABI recording, you can change the occlusion pressure positions; on an AIx|PWV recording, you can move P1, P2 and ED. In addition you can edit the representative cycle and also edit the values L1, L2, L3 in the detailed AIx finding. Activation of this mode is indicated by red cursors (representing the respective parameter's position) and by a change in the screen headings.

Also the Edit icon ![icon] is activated.

Apply changes (Apply ![icon])

This function is not activated unless the Edit mode has been switched on and a parameter has been changed. Once you have moved the cursor to the desired position, the new position of the marker can be saved by clicking ![icon] . The cursors turn blue/grey again and the finding is re-generated.

The respective screen is marked "(manual)" in the headline.

Recalculation (Recalc ![icon])

If you want to re-plot the automatically determined parameters, you can recalculate them by clicking ![icon] . Depending on the calculation power of the computer in use recalculation may take up to one minute.

NOTE!   The parameters can only be reset when the Edit mode is on.

To cancel the Editing mode without making changes, reclick on ![icon] .

6.6   Manual findings

The ABI+AIx software allows for two ways of interpreting the findings:

- An automatic finding made by the software in the sense of a "second opinion".
- A manual finding that is to rendered by the attending doctor and verified.

For every tab, the lower margin of the program window contains an area where manual findings can be faded in and out. When the area is faded out, you see the button for the manual finding on the lower left. With one click, you can fade in the finding. The [icon] button is located in the headline on the right. Use this button to permanently anchor the area in the program window. The button toggles to [icon]. By clicking the button again, you can fade out the finding.
You can resize the area by dragging the upper margin by left clicking the mouse button.

Within this area, you can enter and edit any text which will be displayed under "FINDINGS" in PATIENT EXPLORER.
Using the left buttons, you can paste in text from the clipboard, and cut, copy and delete highlighted text from the finding, and undo any changes.

NOTE!   The PATIENT EXPLORER only shows the manual finding.
                 In the case of a combined ABI + AIx recording, there is only one combined manual finding.

6.7   Blood pressure findings

The "Blood pressure findings" view displays the analysis of the blood pressure values obtained and classifies them according to WHO criteria.
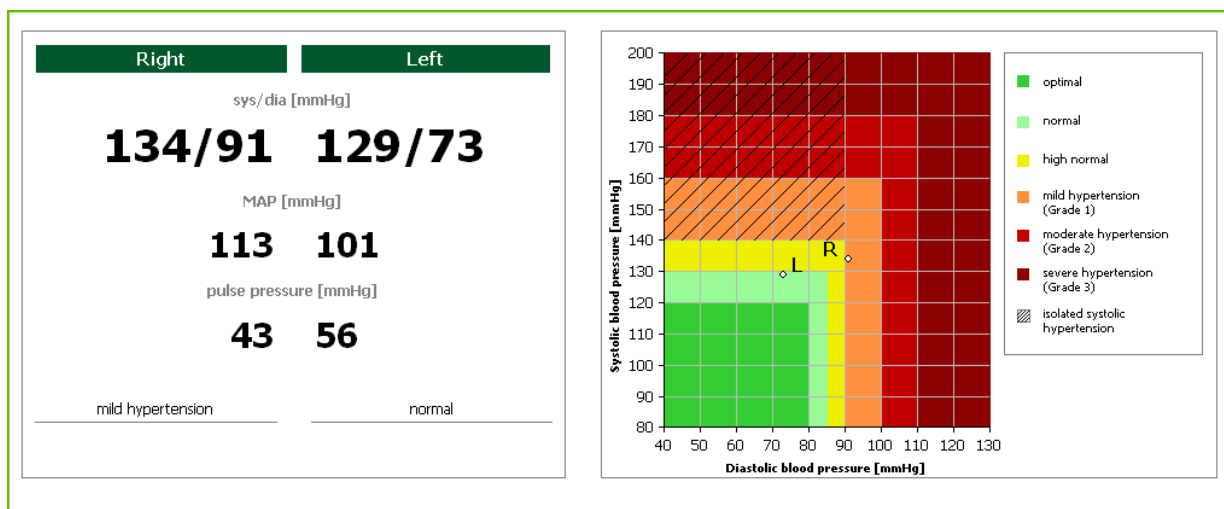

Fig. 8: Blood pressure findings

The pressure values are indicated on the left side and the classification of the blood pressure values appears in the lowermost line (see legend to the right).
In the graphic on the right, each of the values is labeled with "R" or "L".
The color display matches that of the information bar.

7   ABI – DATA RECORDING

The VASCULAR EXPLORER must be switched on before the first measurement is taken.
If the VASCULAR EXPLORER is not properly connected or not turned on, you will be notified by a message blinking in red at the bottom left of the wizard.

When the VASCULAR EXPLORER is connected properly, this is where the device's serial number will be displayed.
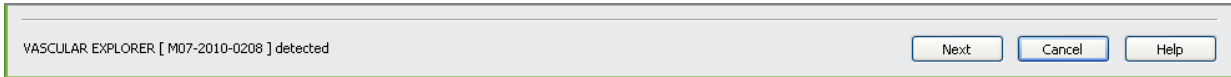

Fig. 9: Hardware found!

Prepare the patient and attach the VASCULAR EXPLORER cuffs and sensors as described in Section GENERAL PROCEDURES.

7.1   Starting a recording

- Start the PATIENT EXPLORER.
- Create a new patient record or select a previously existing patient in the PATIENT EXPLORER.
- Click the "VASCULAR EXPLORER" button in the PATIENT EXPLORER to open a recording mode list.
- You have the option of 4 recording modes "ABI", "AIx", "ABI + AIx" and "Arm AIx". Select the recording mode "ABI" to start the program.

With a running program, you can start a "ABI" recording by pressing the button "ABI" in the top left corner.
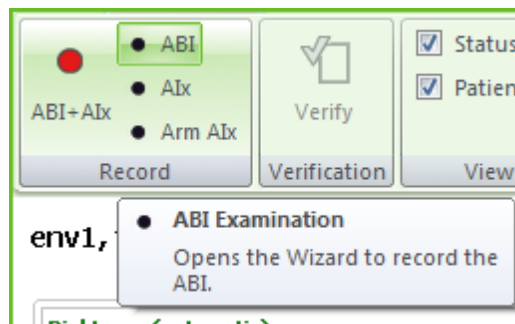

Fig. 10: ABI Recording

- A wizard screen appears to guide you through the recording. You can exit the wizard by pressing the "Cancel" button (see Fig. 11)
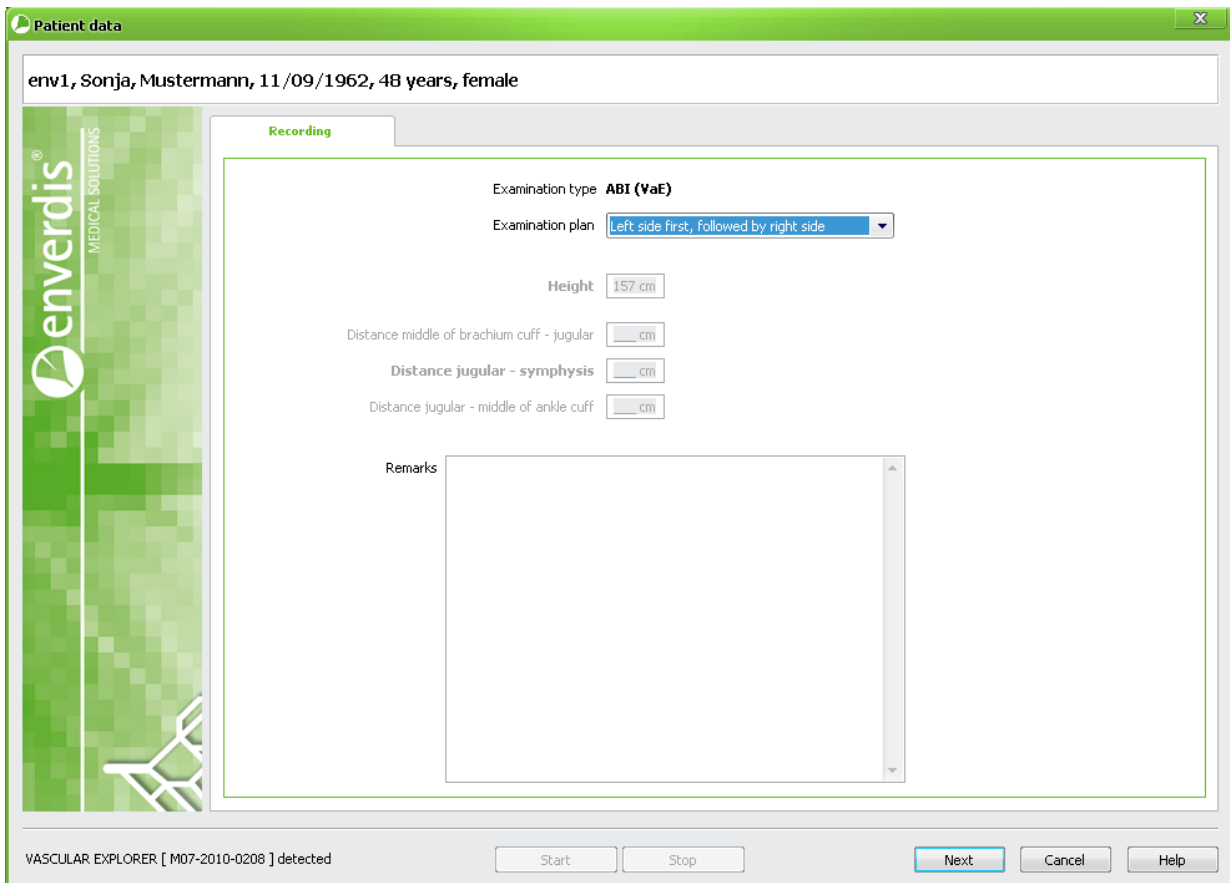
Fig. 11: ABI measurement recording dialog box

You can determine the examination sequence for an ABI recording by selecting the "Examination plan" selection menu.
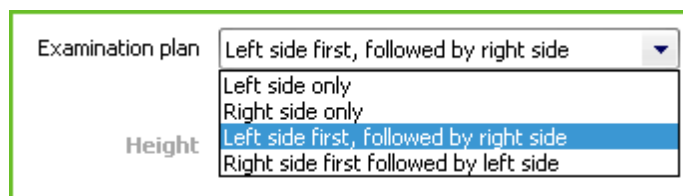

Fig. 12: Recording plan

You have the options to select between "Left side only", "Right side only", "Left side first, followed by right side" or "Right side first, followed by left side". This allows you to individually determine the sequence of an ABI examination.

The information bar is displayed in the headline of the wizard.

Use the field "Remarks" to enter personalized data relevant to each recording. The data are saved separately for this one recording.

Go to the next ABI measurement screen by pressing "Next" (Abb. 13). The way the dialog box is displayed depends on which side was defined first in the examination plan.

Fig. 13: ABI measurement

The schematic diagram depicting a human body helps you assign the finger and toe sensors and cuffs. Optionally, you also have the option to set a different cuff pressure for each extremity.

Use the photoplethysmogram (Fig. 14) to check the proper fit of the sensors and the signal quality. The signal quality is additionally color-coded, with green indicating very good quality.

Abb. 14: Photoplethysmogramm

NOTE!   To ensure optimal recording conditions, do not start the recording until the signal quality is in the green range and the photoplethysmogram is not "jumpy", but appears steady. To ensure optimal analysis of the data the signal quality must be excellent.

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If you are not receiving a good signal, a message will appear on the photoplethysmogram screen, e.g. "Many movement artifacts".

If the signal is "jumpy", check that each of the photoplethysmographic sensors is attached properly and replace them as needed (see Connecting and applying the SPO2 sensors).

Click "Start" to start the examination. The measurement can be interrupted by pressing the "Stop" button. The "Cancel" button or the "ESC" key can be used to cancel the measurement and the wizard.

The curves from the recordings are displayed once the ABI measurement has been completed successfully. About the curves the analysis method is displayed (Plethymographic or Oszillometric).
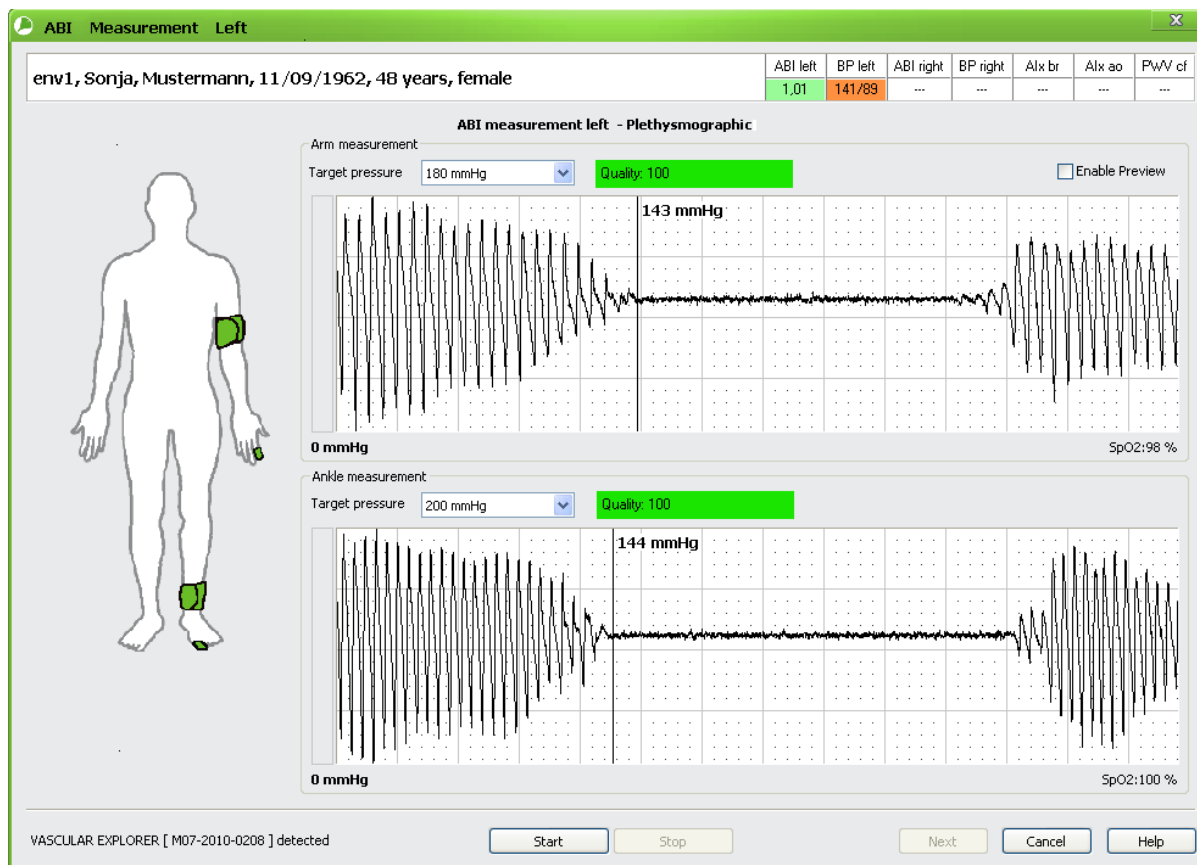

Fig. 15 ABI measurement - left side end

The occlusion position is indicated by a cursor and the corresponding pressure value. By pressing and holding down the left mouse button on the cursor it can be moved. The adjustment is not saved.

Press "Next" to go to the next recording screen. Now attach the cuffs and finger sensors to the other side of the patient's body. Again, you will be prompted by green symbols at the various extremities in the graphic. You will not be allowed to continue the examination until the pre-set recovery phase has expired.

NOTE!   You can change the duration of the recovery phase under "Settings".

After this measurement is completed, you will always have the option to repeat the measurement.

Whenever the occlusion pressure has not been detected, the target pressure has to be increased. A value of 40 mmHg is recommended. Before starting the recording switch to the monitoring mode (check the "Monitoring" box). Now it's possible to assess the signal quality like explained above.

Fig. 16: Button Repeat

After you click "Finish", you exit the wizard and will be taken automatically to the "ABI Writer" view.

The following paragraph explains the different evaluation options for the ABI recording..

The ankle-brachial index (ABI) is a parameter for detecting stenoses or occlusions in the peripheral arteries. The ABI can be used to diagnose peripheral artery occlusive disease (PAOD).
Once you have successfully carried out at least one of the ABI measurements, you can view the automatically generated finding by clicking the "ABI Findings" tab..

A simple and detailed view is available; the setting for this can be changed under the "View" icon group.
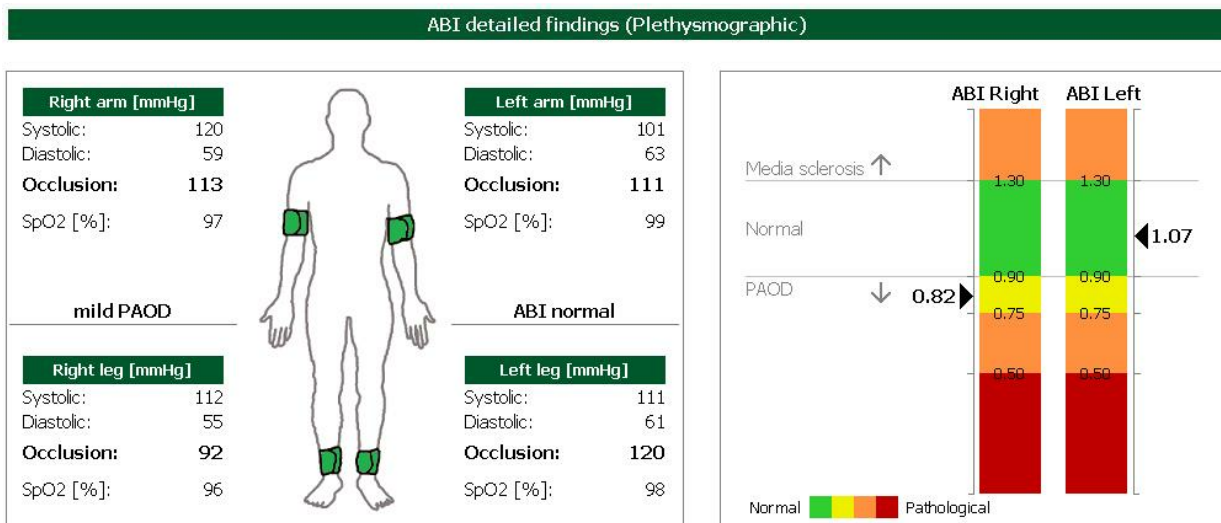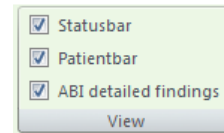

Fig. 17: ABI Findings

This finding will list the relevant closing pressures and the derived ABI. The finding is based on the following classification:

ABI	Finding
>1,3	Media sclerosis
0,90-1,30	Normal
0,75-0,90	Moderate PAOD
0,50-0,75	Moderately severe PAOD
<0,5	Presumed severe PAOD

The ankle-brachial index is calculated from the closing pressure measured in the ankles divided by the mean of the closing pressures measured in the arms.

NOTE!   If the difference between the two closing pressures measured on the arms is < 10 mmHg, the mean of the two values is selected as the closing pressure of the arms; otherwise, the maximum is used.

You will also see a diagram on the right in which the calculated ABI values for the patient have been allocated to color-coded standard ranges (see classification above). The green and yellow areas indicate the normal range. Orange to red points to clinical pictures such as media sclerosis or PAOD .

It is possible to switch to oscillometric findings if the photoplethysmographic findings are challenged due to signal noise or poor signal quality. This way of ABI determination uses the oscillometrically measured systolic blood pressures of the respective limbs. Toggling between plethysmographic and oscillometric assessment is available in edit mode only.

Making changes to this section will cause the finding to be automatically adapted and the values to be updated in all tables and graphics. If you want to save this setting, you must apply the changes.

7.3   ABI curves

Use the "ABI Writer" tab to access ABI curves (Fig. 1). Here you can view all plethysmograms as desired.

The default setting is that the curves fit the display area. Using the mouse wheel or the context menu (right mouse click), you can change the view. The setting is indicated in the upper right display area (fit, manual, 50% to 500%). If the signal length extends beyond the display area, you can move the display in a horizontal direction by holding down the left mouse button and dragging the mouse.
By simultaneously pressing the Ctrl key and the left mouse button, you can define a rectangle in the display area which represents the new area, i.e. this designated area will now be displayed.

Hide or view the corresponding windows by pressing the single arrows along the edge of the window.
Additionally, you can change the size of the display areas by dragging their middle borders using the left mouse button.

By clicking the ⬚ button, you can centre the cursor of the closing pressure position of a plethysmographic ABI recording on the screen.
You can drag the occlusion pressure position using the left mouse button; however, changing the value is persistent in the Edit mode only.

7.4   Editing occlusion pressure positions

The editing function is used to correct automatically detected closing pressures. You can use your own discretion to make any fine adjustments to the closing pressures on the plethysmogram. Once the finding has been verified, you can no longer activate the Edit mode.

How it works

To edit occlusion pressure positions, use the ⬚ , ⬚ and ⬚ buttons. When the Edit mode is switched on, the occlusion pressure positions appear in red and can be moved at random. The pressures for each extremity can be redetermined separately. To save the new positions, click "Apply" and the findings will be updated.

Use "Recalc" to return the closing pressures back to the automatically detected positions in the photoplethysmogram.

To cancel the Editing mode without making changes, reclick on ⬚ .

8   AIx│PWV – DATA RECORDING

8.1   Starting a recording

Prepare the patient and attach the VASCULAR EXPLORER cuffs as described in Section <u>GENERAL PROCEDURES</u> .

- Start the PATIENT EXPLORER.
- Create a new patient record or select a previously existing patient in the PATIENT EXPLORER.
- Click the "VASCULAR EXPLORER" button in the PATIENT EXPLORER to open a recording mode list.
- You have the option of 4 recording modes "ABI", "AIx", "ABI + AIx" and "Arm AIx". Now, please select the "AIx" recording mode to start the software.

With a running program, you can start a "AIx" recording by pressing the button "AIx" in the top left corner.
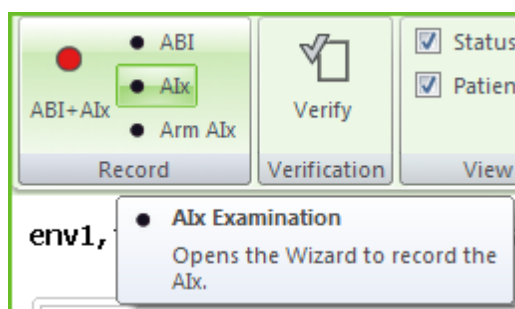

Fig. 18: AIx recording

A wizard screen appears to guide you through the recording. You can exit the wizard by pressing the "Cancel" button (Fig. 19). Apart from the patient's body height, here you must enter three important distances which are required for the calculation of the AIx and PWV. The "Distance suprasternal notch - pubic bone" is a mandatory field. In the finding, missing distances are indicated as not existing by "---". The same applies to the dependent PWV ba(1). The PWV ba(2), on the other hand, is calculated from the distances estimated from the body height.

The <u>information bar</u> is displayed in the headline of the wizard.
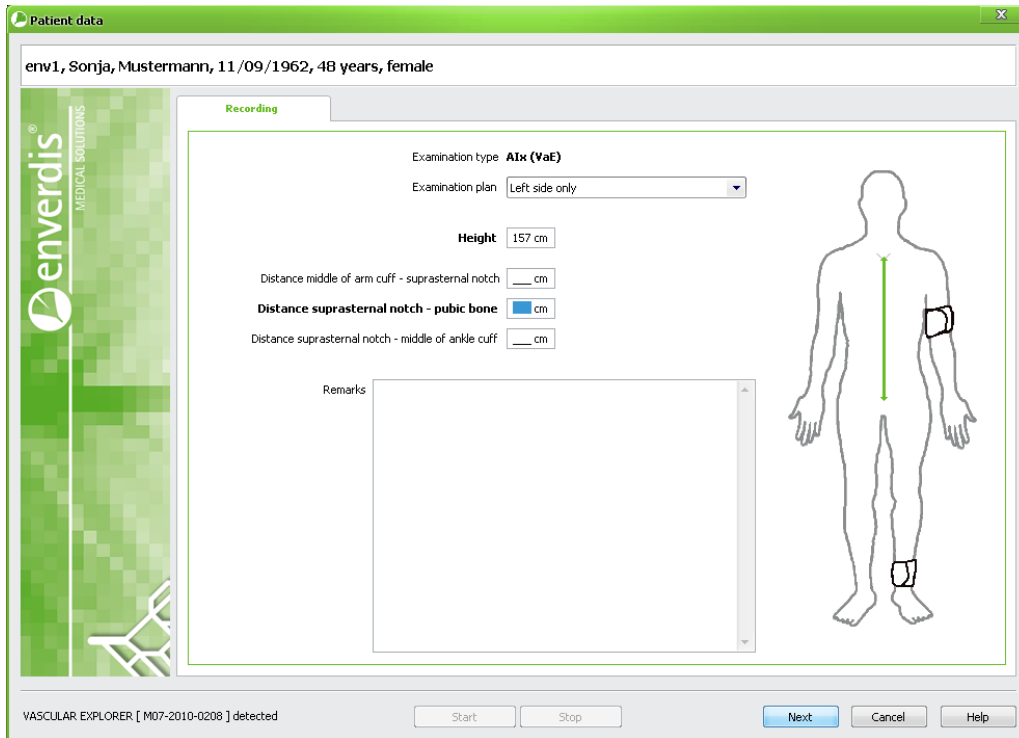
Fig. 19: AIx measurment recording dialog box

During distance measurements, the patient should be standing up straight or lying stretched out on an examination table. The name of each measuring site is stated next to the entry field and also indicated on the schematic diagram by green arrows. For determining the distance from the middle of the arm cuff to the suprasternal notch, the patient should extend their arm at a right angle to their body.

In the examination plan, you have defined the order for carrying out the measurements on the patient.

Once you have fitted the cuffs and filled in the highlighted fields, you go to the AIx blood pressure measurement window (Fig. 20) by pressing "Next".
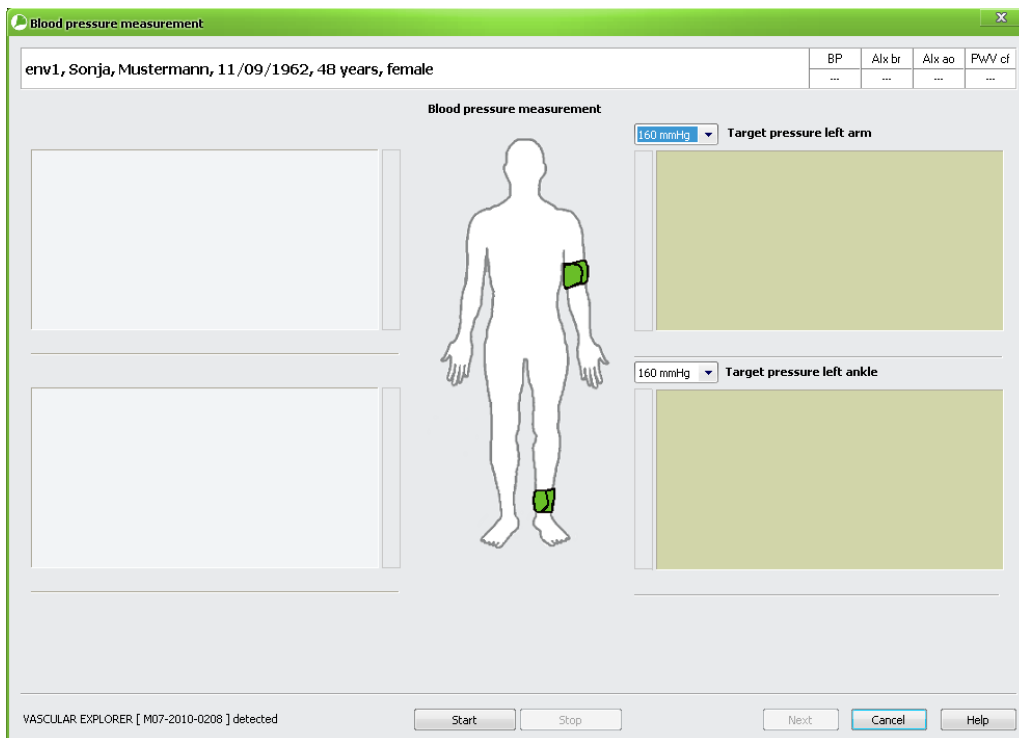

Fig. 20: AIx blood pressure measurement

Before the Alx recording, a blood pressure measurement is taken to determine the diastolic and suprasystolic pressure levels.

The cuffs marked in green on the person in the diagram indicate the side on which readings will be taken. Start the blood pressure reading by pressing "Start".

After this measurement, the recovery time you have set under "Settings" (see "Settings") will be displayed. If the relax time is expired you can repeat the recording by pressing "Repeat". Go to the Alx measurement screen by pressing "Next".
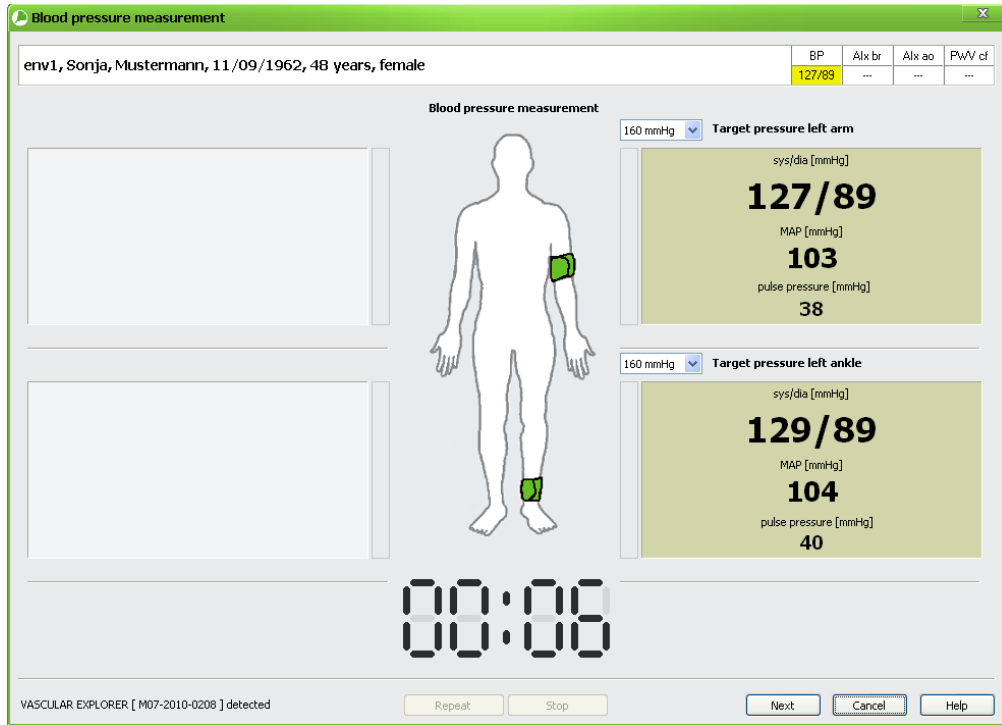

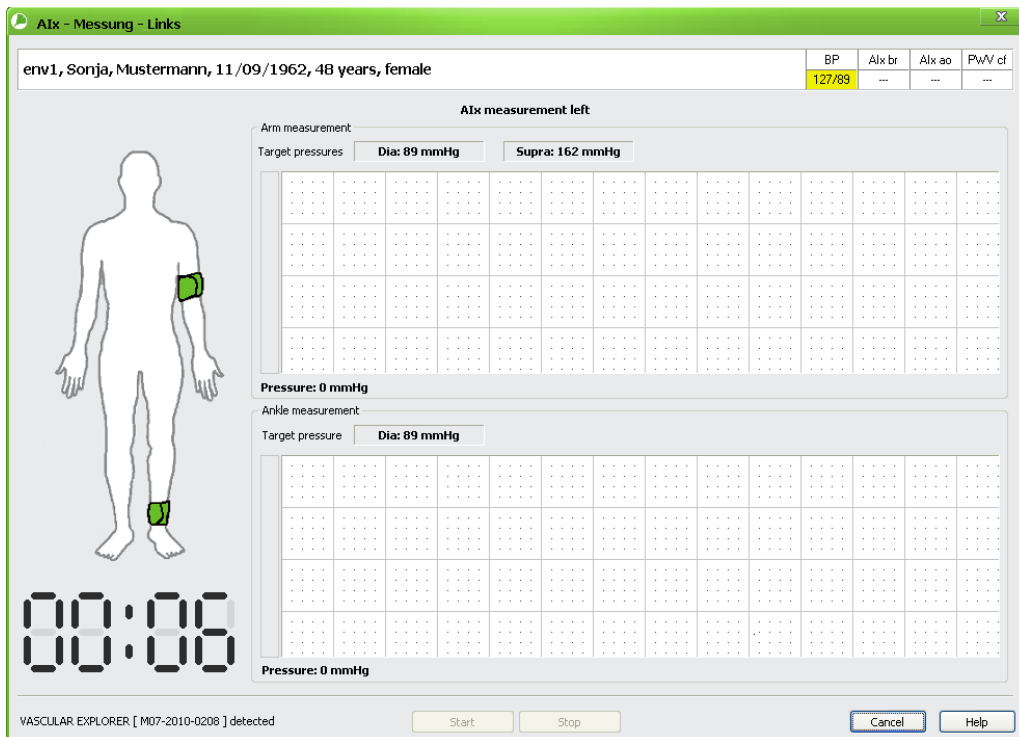
Fig. 21: Alx blood pressure measurement end

Fig. 22: Recording side Alx measurement

The "AIx" recording can be started, when the relax time is expired.
Next, the cuffs will be inflated to the diastolic pressure. This pressure is maintained for 15 seconds, during which time the diastolic pressure curve is plotted.

NOTE!   Throughout the recording, the patient should lie still, not speak or cough and try to breathe as shallowly as possible.

The pressure in the ankle cuff is released and the arm cuff is inflated to the suprasystolic cuff pressure, i.e. 35 mmHg above the systolic blood pressure. This pressure is maintained for 15 seconds and then released again.

NOTE!   Each step of the measurement is indicated by text on the AIx measurement screen.

The curves from the recordings are displayed once the AIx measurement has been completed successfully.
Click the "Repeat" button to activate a new measurement.
After you click "Finish", you exit the wizard and will be taken automatically to the "AIx Writer" view.

8.2 AIx|PWV evaluation

8.2.1 AIx findings

The following paragraph explains the various evaluation options for the AIx|PWV recording.

The AIx is used to determine the arterial elasticity, which in turn can be used to estimate the cardiovascular risk.

The software will automatically create a representative beat during which the parameters augmentation index (AIx) and pulse wave velocity (PWV) are determined.

The AIx is determined by establishing the two maxima P1 (peak of the first pulse wave) and P2 (maximum of the reflected pulse wave) as well as the foot point.

The figure below (Fig. 23) illustrates sample curves from a young and from an elderly adult, indicating the basis points.
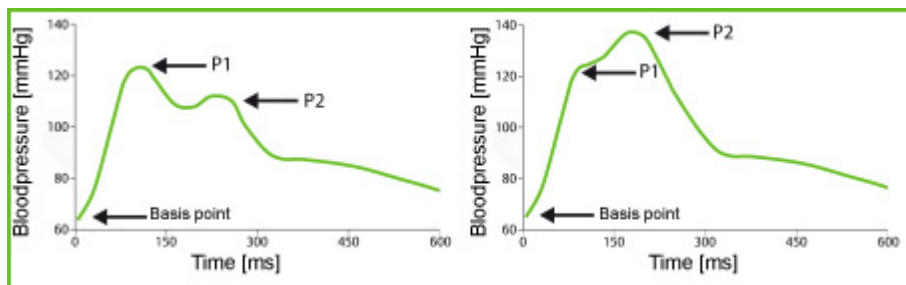

Fig. 23: Pressure curves for a healthy adult aged 30-40 years (left) and a healthy adult aged 60-80 years (right)

The AIx is calculated for the brachial artery (AIx br) and the aorta (AIx ao). Additionally, the AIx of the aorta is normalized to 75 bpm and rendered as AIxao@75.

In the table, you will find the following limit values for evaluating the brachial AIx shown in the finding:

AIx$_{br}$	Finding
<-30%	optimal
-30%<AIx br<-10%	normal
-10%<AIx br<10%	elevated (reduced arterial elasticity)
AIx br>10%	pathological: Reduced arterial elasticity and increased cardiovascular risk

The aortic pulse wave velocity (PWV ao) is another parameter for evaluating arterial stiffness independently of the AIx. This parameter is determined from the distance between the suprasternal notch and the pubic bone (or aortic root / aortic bifurcation) and the time difference between P1 and the reflected pulse wave. The PWV ao is indicated in m/s.

The brachial ankle PWV is calculated from the distance from the centre of the arm cuff to the centre of the ankle cuff and the time difference between the signals recorded on the ankle and the arm.

In addition to the aortic PWV, the carotid-femoral PWV (PWV cf) is displayed. The PWV cf value was validated and calibrated by an internal test using SphygmoCor®.

The table shows the following limit values for evaluating the PWV cf displayed in the finding:

PWV_{cf}	Finding
< 7,0 m/s	optimal
7,0 m/s = PWV_{cf} < 9,7 m/s	normal
9,7 m/s = PWV_{cf} < 12,0 m/s	elevated
>12,0 m/s	pathological

8.2.3   Automatic findings

Once you have successfully carried out the measurements, you can view the automatically generated finding by clicking the "AIx Findings" tab.

A simple and detailed view is available; the setting for this can be changed under the "View" icon group.
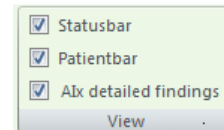
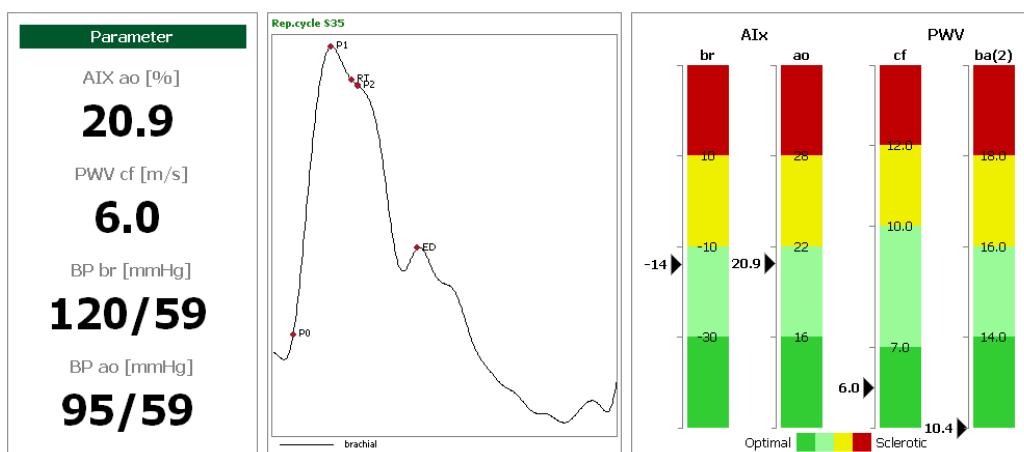Figure 24.1 shows the simple findings.

Fig. 24.1 AIx|PWV Findings

Figure 24.2 shows the detailed findings
The Finding view shows the representative diastolic pressure curves for the arm along with the automatically detected points.
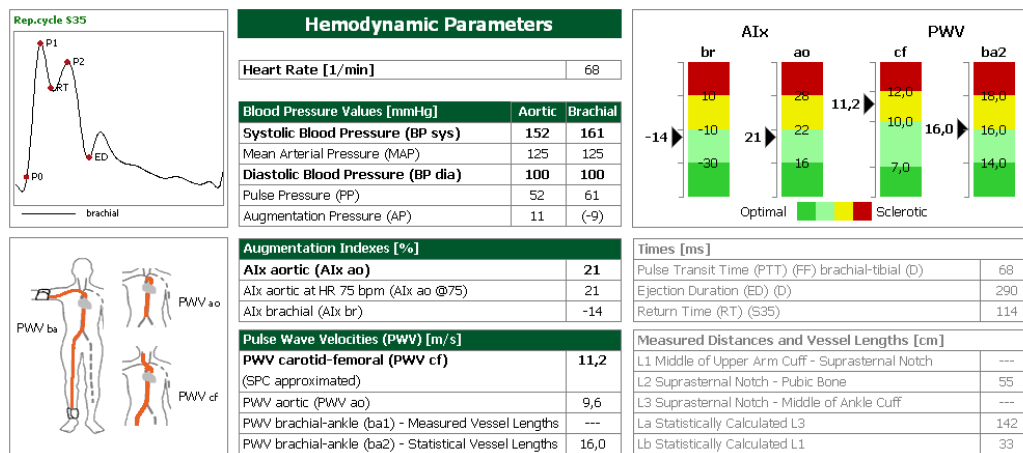
Fig. 24.2: AIx|PWV Findings (detailed)

The finding values obtained are presented in both tables and colored graphics. The colors in the right-hand graph provide a general guide for arterial stiffness that is not related to the patient's age.

This view additionally presents all the measuring values entered along with the calculated arterial lengths and times (Fig. 24.2).

NOTE!   The results generated by the automatic diagnosis program must always be checked and verified by a physician if they are to be used for the final finding.

8.2.4 Editing the lengths

Switch to the Edit mode to edit length data L1, L2 and L3 in the detailed AIx finding. The corresponding fields will be highlighted with a red frame.

Measured Distances and Vessel Lengths [cm]	
L1 Middle of Upper Arm Cuff - Suprasternal Notch	
L2 Suprasternal Notch - Pubic Bone	55
L3 Suprasternal Notch - Middle of Ankle Cuff	
La Statistically Calculated L3	142
Lb Statistically Calculated L1	33

Fig. 25: Editing length data

Click (Apply) to permanently accept the values.

8.2.5 AIx Age graphs

In the "AIx Age-Graphs" view (Fig. 26), the estimated age (x axis) is displayed after determination of aortic pulse wave velocity, aortic augmentation index and brachial pulse wave velocity. At the same time, the real age of the patient is also entered in the graphics in relation to the parameters mentioned above. If this point is located below the value curve, then the patient's arterial elasticity is still very good for his age group. In the white region above the curve, the elasticity can be rated as satisfactory. Yellow means the arterial elasticity is already impaired. If the point is in the red area, then the arterial stiffness can be considered to be of great concern.
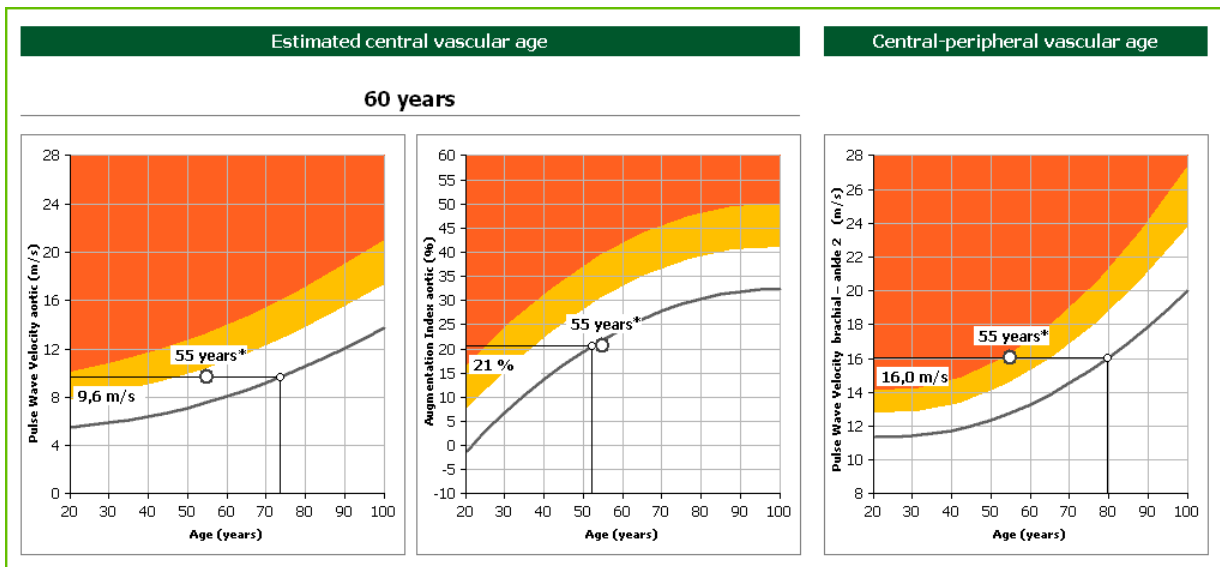
Fig. 26: AIx Age graphs

8.3   AIx pressure curves

Use the "AIx Writer" tab to view the AIx pressure curves (Fig. 27). You can view the curves again here. The representative beats for the diastolic pressure curves and the suprasystolic pressure curve are presented next to the recording.
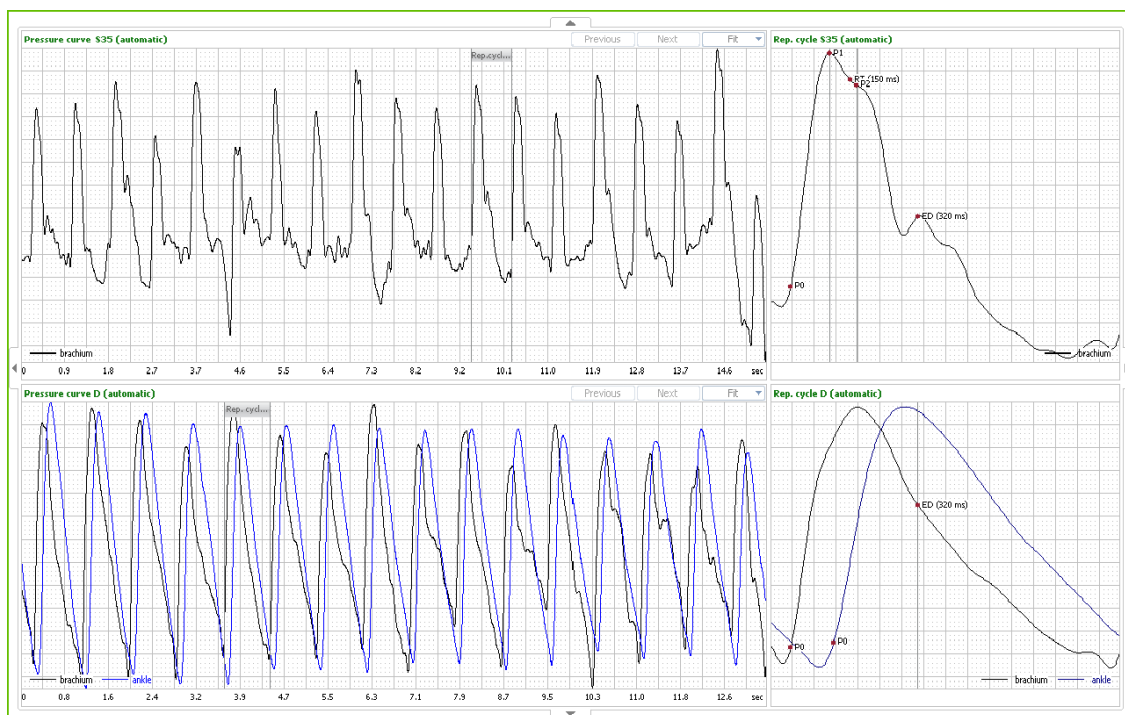

Fig. 27: AIx pressure curves

The default setting is that the curves fit the display area. Using the mouse wheel or the context menu (right mouse click), you can change the view. The setting is indicated in the upper right display area (fit, manual, 50% to 500%). If the signal length extends beyond the display area, you can move the display in a horizontal direction by holding down the left mouse button and dragging the mouse.
By simultaneously pressing the Ctrl key and the left mouse button, you can define a rectangle in the display area which represents the new area, i.e. this designated area will now be displayed.

Hide or view the corresponding windows by pressing the single arrows along the edge of the window.

By clicking the ▨ button, you can centre the representative beat within the display.

8.4   Editing pressure curves

By activating the Edit mode, you can reselect the representative beats and the parameters P1, P2 and ED at your own discretion. When this mode is activated, a red cursor appears (representing the parameter's position) and the screen headings change. In addition, the Editing icon ⌨ is activated.

You can change the representative beat by clicking the buttons "Previous" and "Next" above the corresponding AIx screen. You can also save your changes with "Apply".

Fig. 28: AIx Edit mode

To save the new positions of parameters P1, P2 and ED, press "Apply " ⌷ "; this also updates the findings.

Use "Recalc" ↻ to return the parameters back to the automatically detected positions.

To cancel the Editing mode without making changes, reclick on ⌨ .

9   AIx│PWV – DATA RECORDING – BRACHIAL

9.1   Starting a recording

Prepare the patient and attach the VASCULAR EXPLORER cuffs and sensors as described in Section GENERAL PROCEDURES .

- Start the PATIENT EXPLORER.
- Create a new patient record or select a previously existing patient in the PATIENT EXPLORER.
- Click the "VASCULAR EXPLORER" button in the PATIENT EXPLORER to open a recording mode list.
- You have the option of 4 recording modes "ABI", "AIx", "ABI + AIx" + "Arm AIx". Now, please select the "Arm AIx" recording mode to start the software.

With a running program, you can start a "Arm AIx" recording by pressing the button "Arm AIx" in the top left corner.
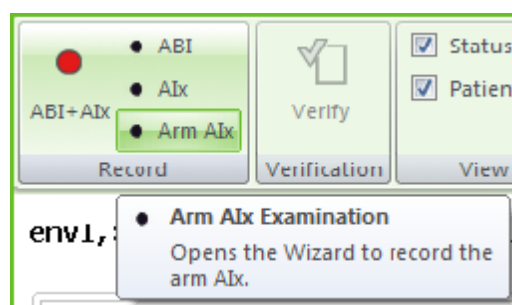

Fig. 29: AIx recording brachial

A wizard screen appears to guide you through the recording. You can exit the wizard by pressing the "Cancel" button. Apart from the patient's body height, here you must enter the distance between the jugular fossa and the symphysis which is required for the calculation of the AIx and PWV.

The information bar is displayed in the headline of the wizard.

During measurements of the distance between the jugular fossa and the symphysis, the patient should be standing up straight or lying stretched out on an examination table. The name of each measuring site is indicated on the schematic diagram by green arrows.

In the examination plan, you have additionally defined the order in which the measurements are to be carried out on the patient.

Once you have fitted the cuffs and have filled in all the highlighted fields, go to the Alx blood pressure measurement window (Fig. 30) by pressing "Next ".
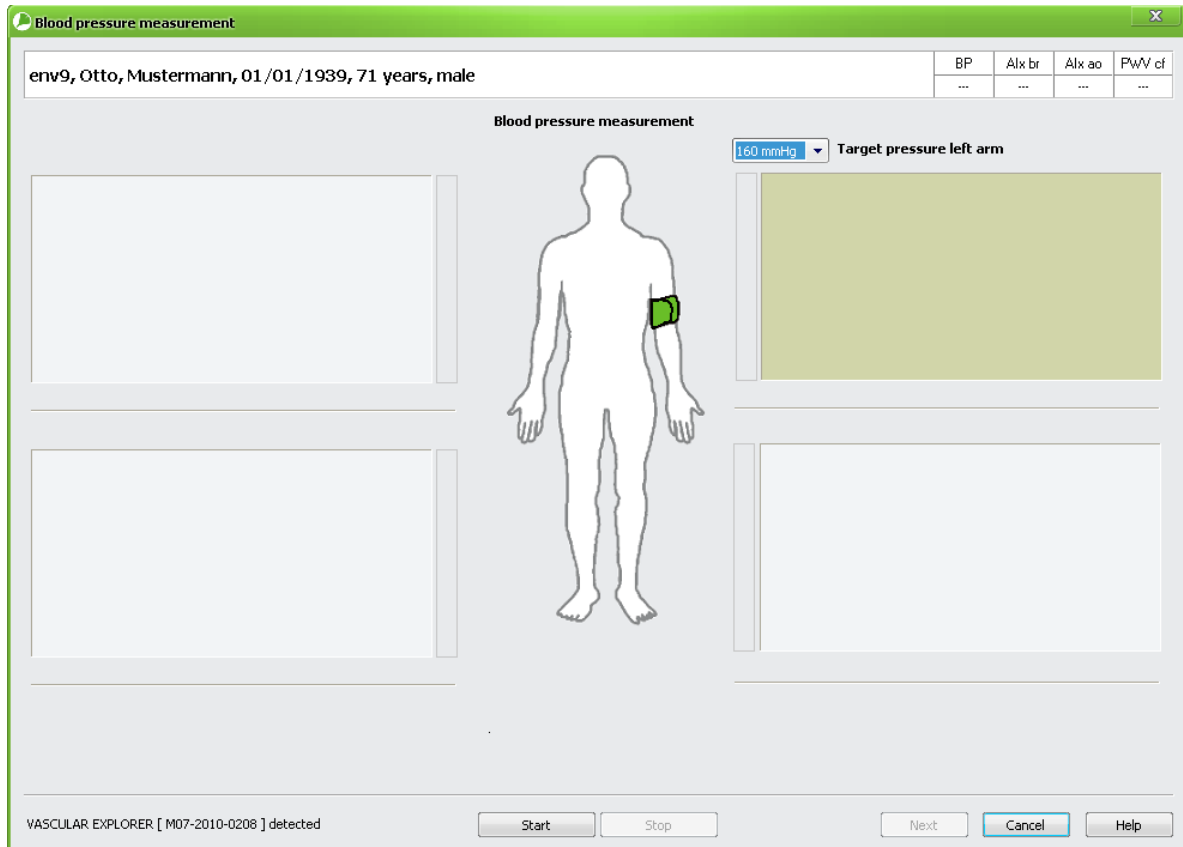

Fig. 30: Alx blood pressure measurement brachial

Before the Alx recording, a blood pressure measurement is taken to determine the diastolic and suprasystolic pressure levels.

The cuffs marked in green on the person in the diagram indicate the side on which readings will be taken. Start the blood pressure reading by clicking on "Start".

After this measurement, the recovery time you have set under "Settings" (see "Settings") will be displayed. If the relax time is expired you can repeat the recording by pressing "Repeat". Go to the Alx measurement screen by pressing "Next".

Start the Alx recording by clicking the "Start" button again. Next, the cuffs will be inflated to the diastolic pressure. This pressure is maintained for 15 seconds, during which time the diastolic pressure curve is plotted.

NOTE!   Throughout the recording, the patient should lie still, not speak or cough and try to breathe as shallowly as possible.

The pressure in the ankle cuff is released and the arm cuff is inflated to the suprasystolic cuff pressure, i.e. 35 mmHg above the systolic blood pressure. This pressure is maintained for 15 seconds and then released again.

NOTE!   Each step of the measurement is indicated by text at the top of the Alx screen.

9.2 AIx|PWV evaluation

Refer to Section "AIx|PWV evaluation" for information about the AIx and PWV findings and the automatic findings.

9.3 AIx pressure curves

Use the "AIx Writer" tab to view the AIx pressure curves (Fig. 31). You can view the curves again here. The representative beats for the diastolic pressure curves and the suprasystolic pressure curve are displayed next to the recording.
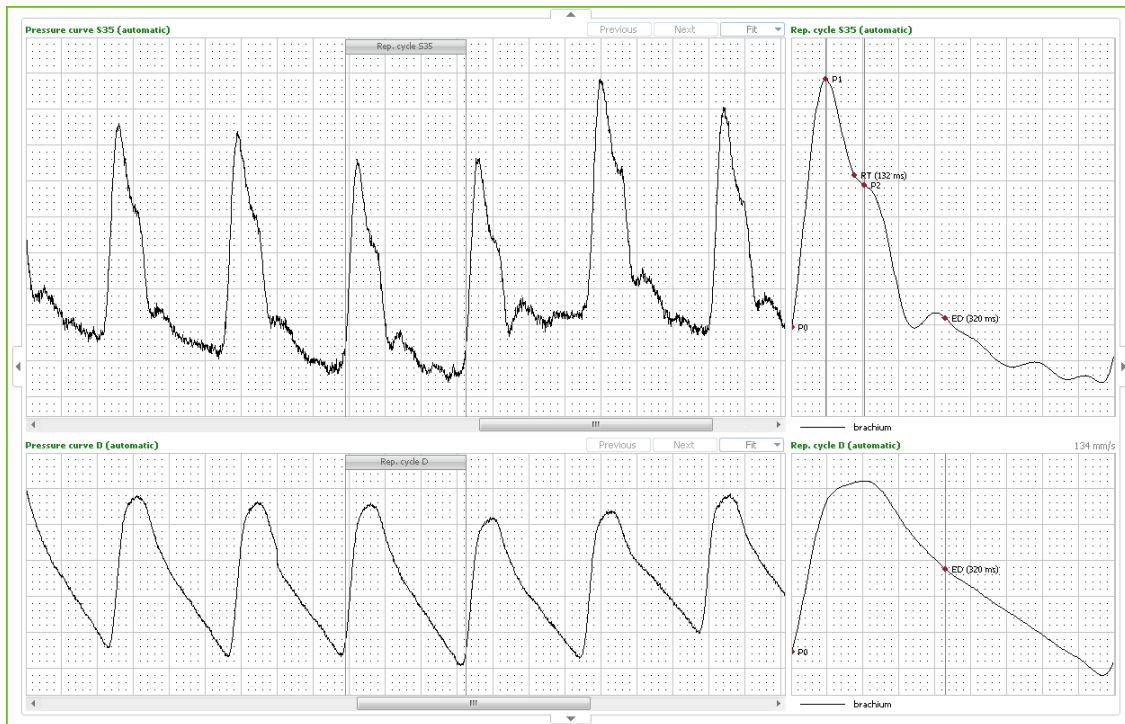

Fig. 31: AIx pressure curves brachial

9.4 Editing pressure curves

The procedure for editing the pressure curves and the parameters is performed as described in Section "AIx|PWV DATA RECORDING".

10 PRINT FUNCTIONS

This section provides information about the ABI+AIx software's print functions.

Click on the button ⎙ to print the current display directly.

Creating screenshots

Click on the button ⎙ to generate a screenshot of the current display and save it in the print manager.

The newly created screenshots have already been selected for printing (thumbnail activated).

NOTE!   When you exit the ABI+AIx software or start a new recording, your saved screenshots will be deleted.

10.1 Print manager

In the default setting, the "Print manager" contains an image of all views of the software module, listed in the catalog on the left-hand side of the screen. By clicking the corresponding selection button, you can include or exclude the view on the printout. The elements in the catalog represent the particular tab.

Toggle to the "Print manager" to display also an overview of all screenshots that you have saved with ⎙.

By using a context menu (hover the mouse over the miniature image and click on right mouse button), you can delete the screenshot or you can use the "Enable" element to include (colored image) the view on the printout or exclude it (gray image).
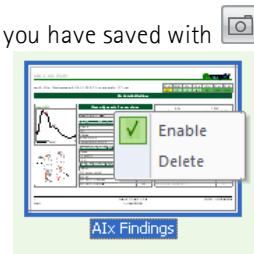
Click ⎙ to print the selected views and screenshots. A pop-up window appears where you can select the printer.
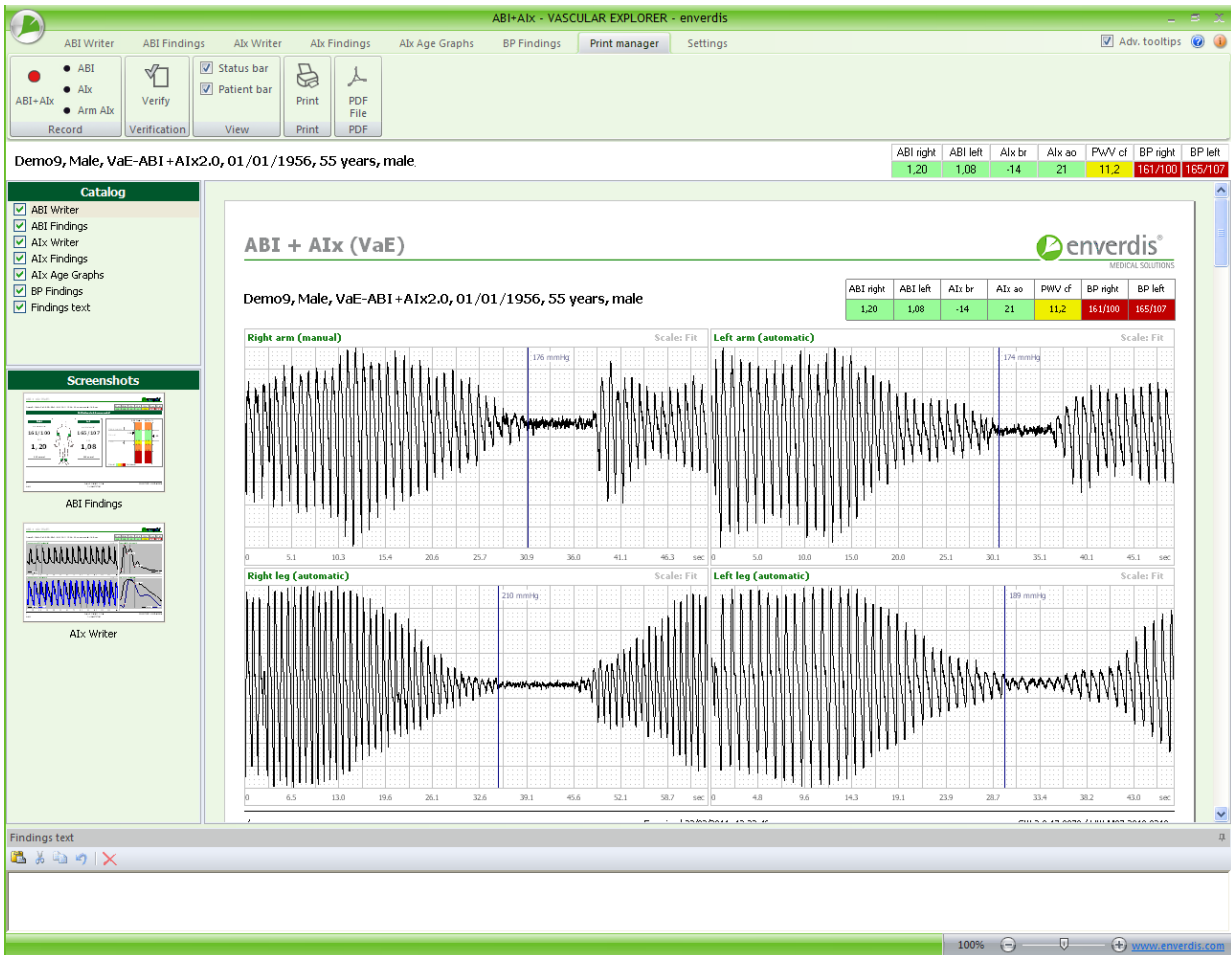
Fig. 32: Print manager

Additionally, the print manager offers you the option to save views and screenshots you have selected in a directory of your choice. To do so, click the [PDF] button.

11 LOADING SAVED DATA

In the PATIENT EXPLORER, you can access saved ABI+AIx recordings.

The PATIENT EXPLORER operator's manual contains information about the use of these functions and the individual features available.
Therein, under the "Assessment of stored recording" menu, you will find a detailed explanation of the individual procedural steps.

You can also start several examinations from the PATIENT EXPLORER, compare them with each other and process them.

12 MANUFACTURER'S INFORMATION

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