User Manual

ABPMpro

Manufacturer

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1 Introduction

Thank you for purchasing this product from SOMNOmedics. Please read the following instruction manual carefully before installing and using the device.

Suggestions to improve the functional characteristics of the device and the instruction for use, we accept at any time. We highly appreciate your feedback. You can contact us using any of the methods listed below.

Our telephone hotline provides competent help and advice throughout the day:

24hours 7days a week +49 (0) 9 31 / 35 90 94 994*

By fax, you can always send us a message quickly:

+49 (0) 9 31 / 35 90 94 49

Via e-mail, you can also communicate your request to us in writing at any time:
service@somnomedics.de

The service login of our website www.somnomedics.de gives you free access to the latest software updates.

* Unfortunately, due to technical reasons, a network failure may occur and therefore the responsible employee cannot be reached immediately. In that case you will be redirected to our mailbox. Please leave a message with your name and telephone number so that we can call you back as soon as the network has been restored.

1.1 Scope

This user manual is meant for the ABPMpro (ABP050) including all the accessories.

Strict compliance with the instructions for use is a prerequisite for the intended and safe use of the device.

1.2 Meaning of symbols in this manual

	Indicates a hint or tip. This symbol provides assistance with possible problems when working with the ABPMpro.
	This warning symbol indicates potential danger to Patients, Property or Data Loss.

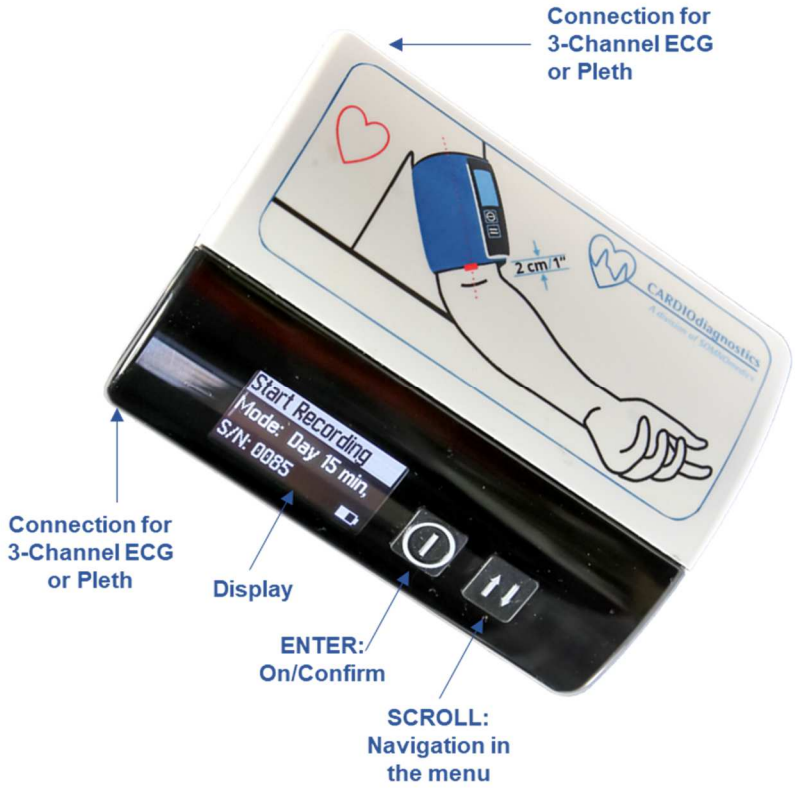
2 About the ABPMpro

The ABPMpro consists of the following hardware:

- ABPMpro recorder with integrated accelerometer and position sensor;
- Brachial blood pressure cuff (3 sizes available to fit the patient's arm size) with integrated 1-channel ECG sensor;
- Optional: 3-channel ECG sensor;
- Optional: pleth sensor;

Depending on the sensor configuration, the recorder may act as a:

1. Up to a 40-hour oscillometric ambulatory blood pressure monitor;
2. 24 hours continuous ambulatory blood pressure recorder;
3. Longterm-3-channel ECG recorder;
4. Mix of the above options.



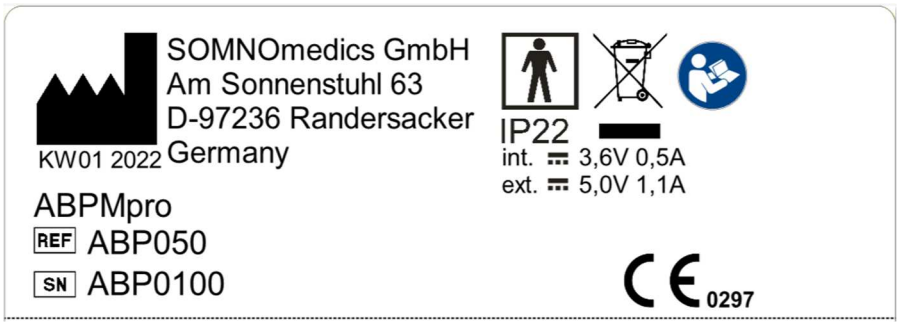
Picture 2-1: Front side ABPMpro

Picture 2-2: Bottom side ABPMpro

Picture 2-3: Integrated ECG electrode in the cuff

2.1 Model and device number

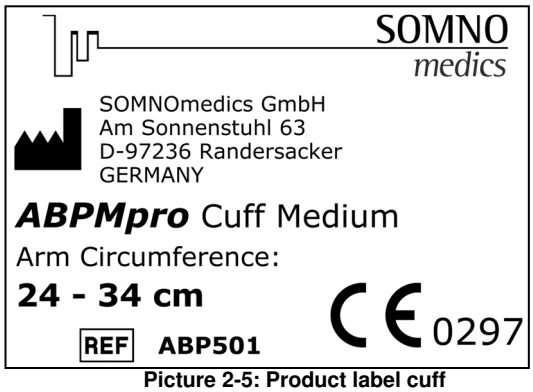
Please ensure, immediately after receipt of the device, that the device is not damaged and that the accessories ordered are included, according to the delivery note. The model name on the product label (at the back of the device) should be ABPMpro and the reference number ABP050.



Picture 2-4: Product label ABPMpro

Product label ABPMpro – Information, symbols, icons and classification on this label

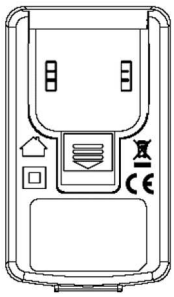
	Read the instruction manual very carefully before you start working with the ABPMpro
	Manufacturer printed right from this symbol, underneath as soon the week plus year of manufacture
REF	Reference number
SN	Serial number
	The device complies with protection class BF
	Used electrical appliances must not be disposed of with household waste
CE	The CE mark indicates that the device complies with all applicable EU directives and has been declared to be in conformity with the manufacturer. The number is the reference of the notified body.
IP22	This device complies with IP protection class 22 (drip-water protection)
int. ⎓ 3,6V 0,5A	Specification of the internal operating voltage and power consumption
ext. ⎓ 5,0V 1,1A	Specification of the external operating voltage and power consumption



Picture 2-5: Product label cuff

Product label Cuff ABPMpro – Information, symbols, icons and classification on this label

	Manufacturer printed right from this symbol
REF	Reference number
CE	The CE mark indicates that the device complies with all applicable EU directives and has been declared to be in conformity with the manufacturer. The number is the reference of the notified body



Picture 2-6: Symbols on power supply ABPMpro

Important symbols on power supply ABPMpro model GTM46101-1005-USB

	GlobTek Manufacturer printed right from this symbol
	The power supply is intended for indoor use only
	Used electrical appliances must not be disposed of with household waste
	The power supply meets the requirements of protection class II and does not need any additional protective conductor connection
CE	The CE mark indicates that the device complies with all applicable EU directives and has been declared to be in conformity with the manufacturer

2.2 Controls

Button	Function
	On/Off and confirm
	Scroll button and patient marker

2.3 Configuration

The ABPMpro consists of the following hardware:

- ABPMpro recorder with integrated accelerometer and position sensor;
- Brachial blood pressure cuff (3 sizes available to adapt to the patient's arm size) with integrated 1-channel ECG sensor;
- Optional: 3-channel ECG sensor;
- Optional: pleth-sensor (led);

Depending on the sensor configuration, the recorder can be used as:

1. 24-hour oscillometric ambulatory blood pressure measurement recorder;
2. 24-hour continuous ambulatory blood pressure measurement recorder;
3. 24-hour 3-channel ECG recorder.

2.4 Intended use

2.4.1 Medical intended use

The ABPMpro is a portable device for recording physiological signals. The ABPMpro is used as a long-term blood pressure as well as a long-term ECG device.

2.4.2 Users and context of use

The ABPMpro is a portable device worn on the upper arm by means of a cuff and used as an oscillometric 24h ambulatory blood pressure recorder.

The ABPMpro consists of the following hardware:

- ABPMpro recorder with integrated accelerometer and position sensor;
- Brachial blood pressure cuff (3 sizes available to adapt to the patient's arm size) with integrated ECG electrodes
- Optional: 3-channel ECG sensor
- Optional: Plethysmogram-sensor (LED)

The ABPMpro records, accumulates and stores the following data:

- Oscillometric based systolic, diastolic and mean arterial blood pressure
- Pulse (based on oscillometric measurements)
- Continuous 1-channel ECG
- Continuous motoric activity
- Continuous body position
- Battery voltage
- Pressure curve

Optional the following data can be recorded:

- Continuous pulse wave
- Continuous 3-channel ECG and cardio impedance

The recorded data by the ABPMpro recorder in combination with the ABPMpro software suite provides:

- Sleep-wake status derived from position and activity,
- heart rate derived from the ECG sensors,
- body position based of ext. ECG and
- breathing frequency based on ext. ECG.

Optional data:

- Pulse transit time (PTT) derived from the ECG and pleth-signal,
- pulse wave velocity is calculated based on the PTT (by a patented and validated algorithm) allowing the provision of a continuous systolic, diastolic and mean atrial blood pressure,
- PEP (pre-ejection period) based on ext. ECG.
- Based on the pulse wave analysis, central systolic and diastolic blood pressure can be determined.

The medical professional will perform the initial application of the device, will explain the application to the patient and will then observe the first blood pressure measurement. After successfully making the first measurement the recorder automatically runs it's selected program.

The ABPMpro user group includes medical personnel and the patients themselves.
The medical personnel group includes physicians and their medical assistants. Physicians alone may perform the evaluation including diagnosis and reporting. Activities listed below can be delegated under the guidance and responsibility of the physician.

Medical personnel:

- initializing the measurement by selecting the mounting and duration of the measurement
- definition and input of patient data, assignment to the device
- putting on the device and the sensors before the beginning of the measurement
- instructing the patient to put on the device and sensors
- start measurement and calibration of continuous blood pressure
- removal of the device and the sensors after the end of the measurement
- data transfer from the ABPMpro to the analysis PC.

Patient:

- connecting the device and sensor
- basic device (without sensor application) can be removed for a short time for e.g. showering
- removing the device and the sensors after the end of the measurement

2.4.3 Patients

The ABPMpro and its accessories may only be used on patients aged 12 years and older. It may only be used on intact skin.

2.4.4 Indications

The device enables long-term measurements of blood pressure and ECG of up to 24 h duration.

Indications for the use of the ABPMpro are:

ICD - 10	Description
I 10	Essential (primary) hypertension
I 11.9	Hypertensive heart disease without heart failure
I 20.8	Other forms of Angina Pectoris
I 95.1	Orthostatic hypotension
R 03.0	Elevated blood pressure reading, without diagnosis of hypertension
R55	Syncope and collapse
Z01.30	Encounter for examination of blood pressure without abnormal findings
Z01.31	Encounter for examination of blood pressure with abnormal findings

Indication for the use of the ABPMpro are, but not limited to those:

ICD - 11	Description
BA00-BA04	Hypertensive diseases
BA20-BA2Z	Hypotension

2.4.5 Contraindication and exclusions

The device must not be used on patients under 12 years of age.

In the event that accessories, such as sensors, are not applied as specified, a correct measurement result cannot be guaranteed. Especially in the case of children, the application of sensors and the final evaluation of the measurement must be carried out with this circumstance in mind.

In the case of children, measurements may only be performed under supervision.

The system is intended exclusively for diagnostic applications or as a source of data for making a diagnosis. It is not intended for use in life-support and monitoring systems. The use of the ABPMpro and its accessories is excluded for patients requiring monitoring and intensive care.

The ABPMpro is thus not to be used independently or in combination with another product as a life-support or monitoring system. There is no claim to compatibility with diagnostic imaging equipment. The device is not designed for use in the emergency services environment regarding IEC 60601-1-12.

The device must not be operated with HF surgical equipment.

The device is not designed for use in physiologic closed-loop controllers regarding IEC 60601-1-11.

The device is not designed for use in an X-ray environment.

Do not use the device on patients with continuous flow ventricular assist pumps, dialysis shunts, recent surgical wounds and Lymphedema.

Existing cardiac arrhythmias may result in inaccurate blood pressure measurements. The assessment is the responsibility of the physician.

2.4.6 Side effects

Because of pressure on the arm, the cuff and its sensors could cause pressure points on the skin. This will disappear over time.

Also ECG electrodes can cause redness of the skin and/or skin irritation, that will disappear over time.

3 Safety instructions, warnings, cautions and actions to take

Check the device housing, all cables, and connectors for damaged insulation before each use. Damaged parts are no longer to be used and replaced immediately. Only sensors designed and supplied by SOMNOmedics may be used with this unit.

This device is NOT designed to be used in a Life Support situation, surgical rooms, intensive care units, or in emergency vehicles.

Attach the cuff and sensor/electrode wires securely to the patient to avoid strangulation. Fix the sensor cable with adhesive tape if needed.

The devices are not toys. Keep the devices away from children, pets and pests.

The device is not designed for operation in potentially explosive atmospheres or in a combustion-promoting atmosphere.

The device is rated IP22 in terms of moisture and water penetration.

The device must be protected from temperatures below 5°C and above 40°C. In addition, the ingress of dust, dirt and water can damage the device.

If liquids have penetrated the device, they must be removed immediately by SOMNOmedics Customer Service and the device must undergo a safety inspection. Do not use the device in such a case.

If the unit is stored for a long time, it should be kept in a closed room to prevent condensation due to high humidity variations in temperature.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ABPMpro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Avoid the use of radios in the immediate vicinity of the device. High frequency operation equipment, wireless (mobile) telephones, CB radios, microwave ovens, etc., through which the electric fields could exceed 10 V / m (in accordance with standard IEC 60601-1-2).

Electrostatic discharge (ESD) can cause artifacts in the device's signal. Avoid conditions where electrostatic charges may form on carpets, clothing and sheets of synthetic fibers due to low humidity and friction.

During application, conductive parts or the plug of the ECG sensor must not come into contact with other conductive parts, including earth.

WARNING: Use of accessories, transducers, cables or mains supply other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The device is not designed for use with HF surgical devices.

On patients with cardiac pacemakers or other implanted stimulators, the cardiac impedance analysis MUST be turned off during the initialization by selecting the pacemaker detection or the external ECG should not be used.

Follow the manufactures instructions when using disinfectants. Keep to the prescribed dose and contact time.

Opening the case, repairing or modifying the ABPMpro in any way will void the guarantee. Only SOMNOmedics and its authorized distributors may repair the unit.

Damaging the Guarantee Seal “Warranty void, if seal is broken” will immediately void the guarantee of this ABPMpro product.

The device is not protected against discharge from a defibrillator.

Measurements include personal data stored on the PC. Therefore, all necessary measures must be taken to protect this data (e.g., automatic timed logoff of user sessions, limiting physical and network access to the storage device, use of multilayer authentication, strong passwords).

Too frequent measurements may cause injury due to blood flow interference, make sure to keep a minimum of 1 to 1.5 minute between two consecutive measurements, to allow the blood circulation in the arm to recover.

In case external devices are connected to the same limb as the ABPMpro system and are placed underneath or below the cuff this could lead to temporarily loss of function or artefact afflicted signals.

If a prolonged impairment of the circulation of the blood is observed, take the device immediately off the cuff to have the pressure released in the cuff straight away.

4 Software preparations

4.1 System requirements

ABPMpro Software	Minimum	Recommended
Operating system	Windows 10, 64 bit	Windows 10, 64 bit
RAM, Processor	4 GB, Intel i5	16 GB, Intel i5
Connections	1x USB 2.0	1x USB 2.0
Harddrive	1 GB (SSD)	Min. 10 GB Max. 2 TB (SSD)

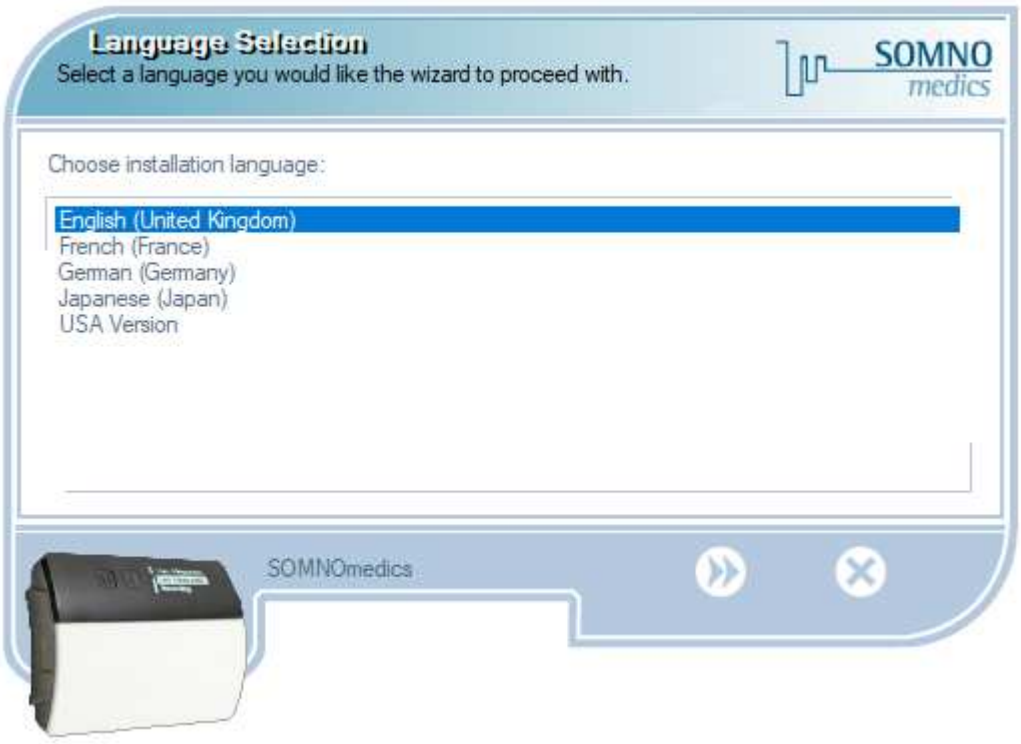
Use appropriate antivirus software and a firewall to protect your system from malware.

4.2 Installation of the ABPMpro software

Please check the above-mentioned system requirements for the ABPMpro software. Only use an installation file that comes from a trusted source, like delivered along with the system, provided by our distributor or downloaded from our website (customer login).

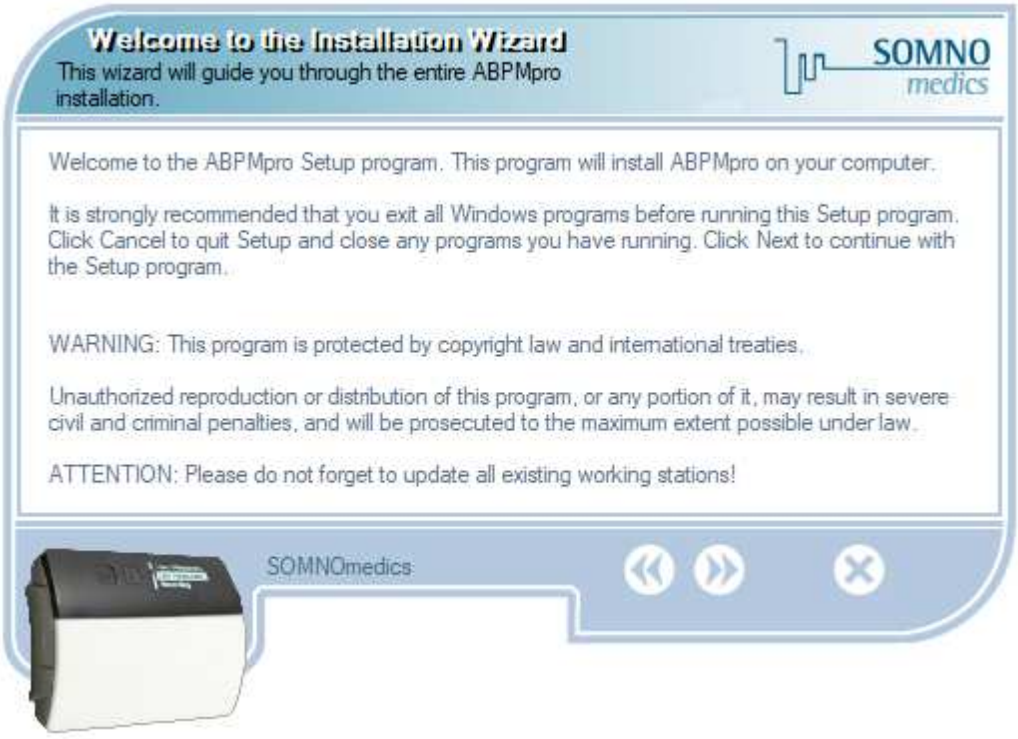
The installation file is setup_x64.exe.

Please select the wished Language and then press , to go to the next window.



Picture 4-1: ABPMpro software installation

Confirm the welcome message by pressing .



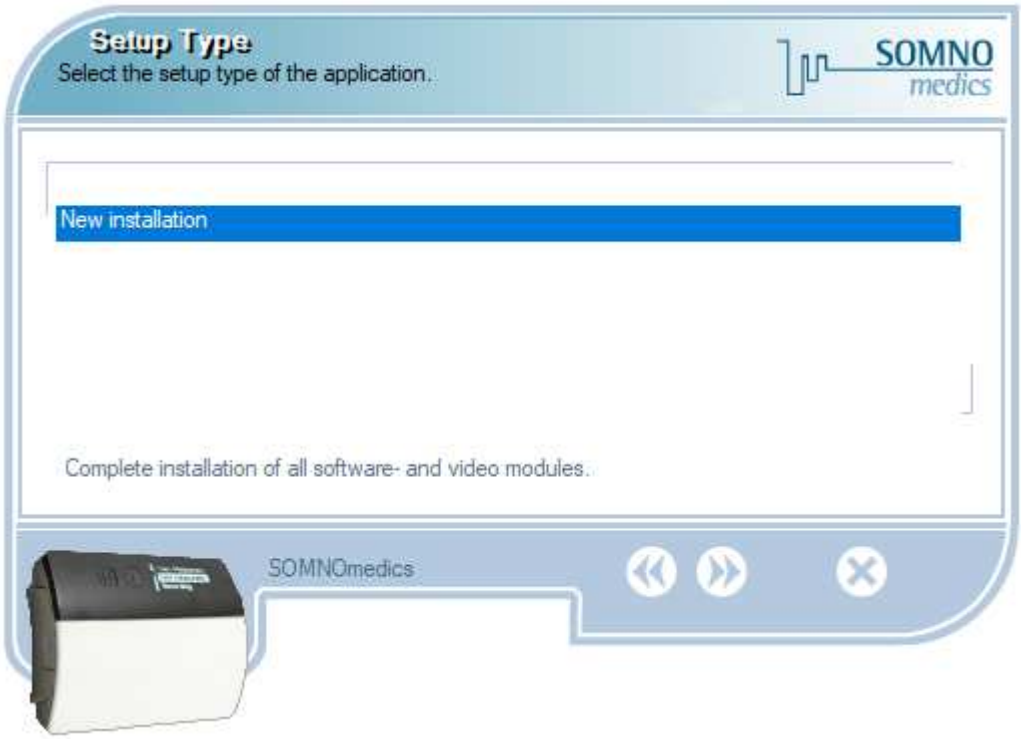
Picture 4-2: ABPMpro software installation

Confirm the default installation folder or adapt the folder by clicking “Browse…”, please **DO NOT** install the software in the Program Files Folder of Windows as this could lead to the software not working correctly.

Then confirm by pressing .

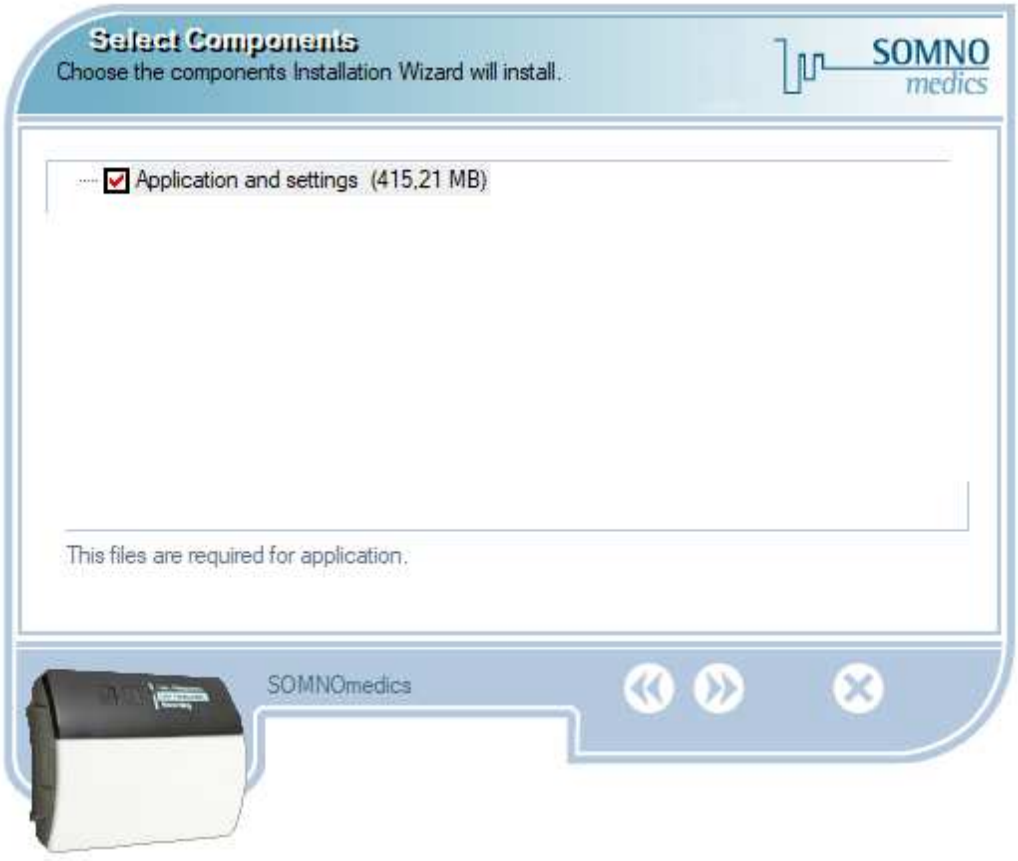
Picture 4-3: ABPMpro software installation

Confirm the new installation by pressing .



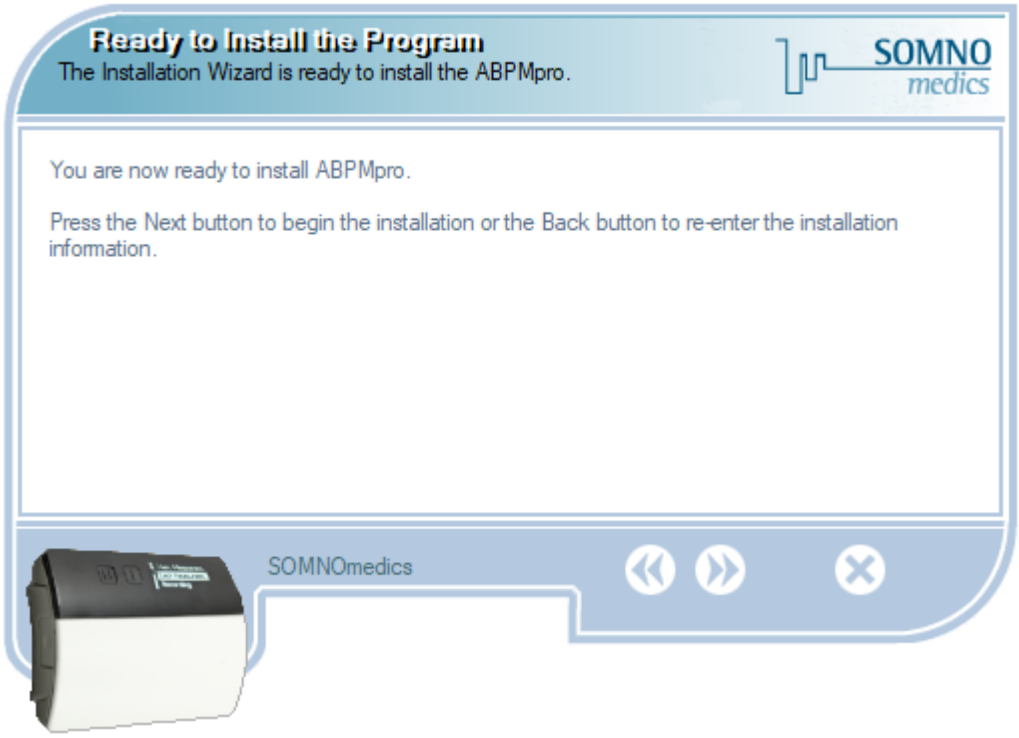
Picture 4-4: ABPMpro software installation

Select the components that have to be installed and press .



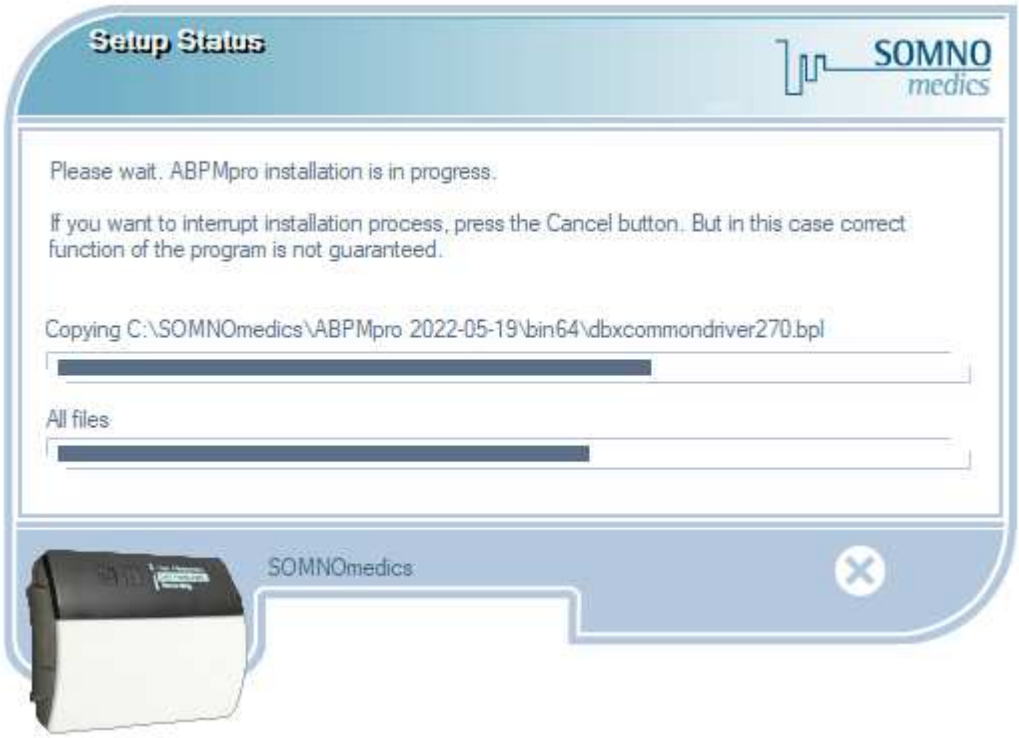
Picture 4-5: ABPMpro software installation

To start the actual installation, confirm this screen by pressing .



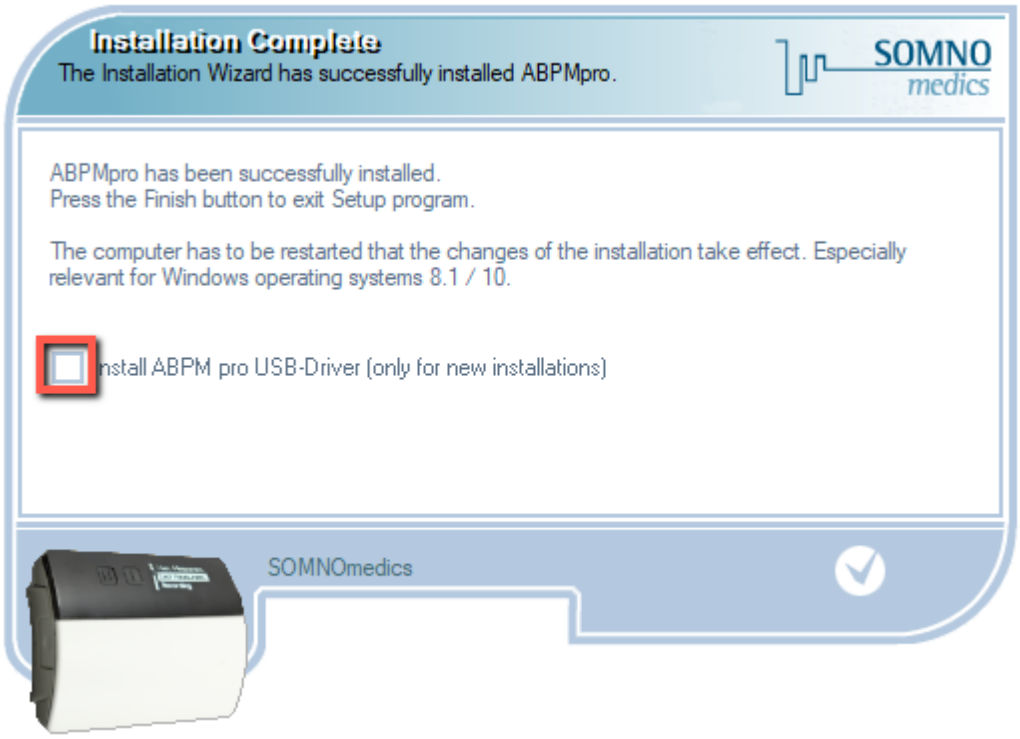
Picture 4-6: ABPMpro software installation

The installation will now run.



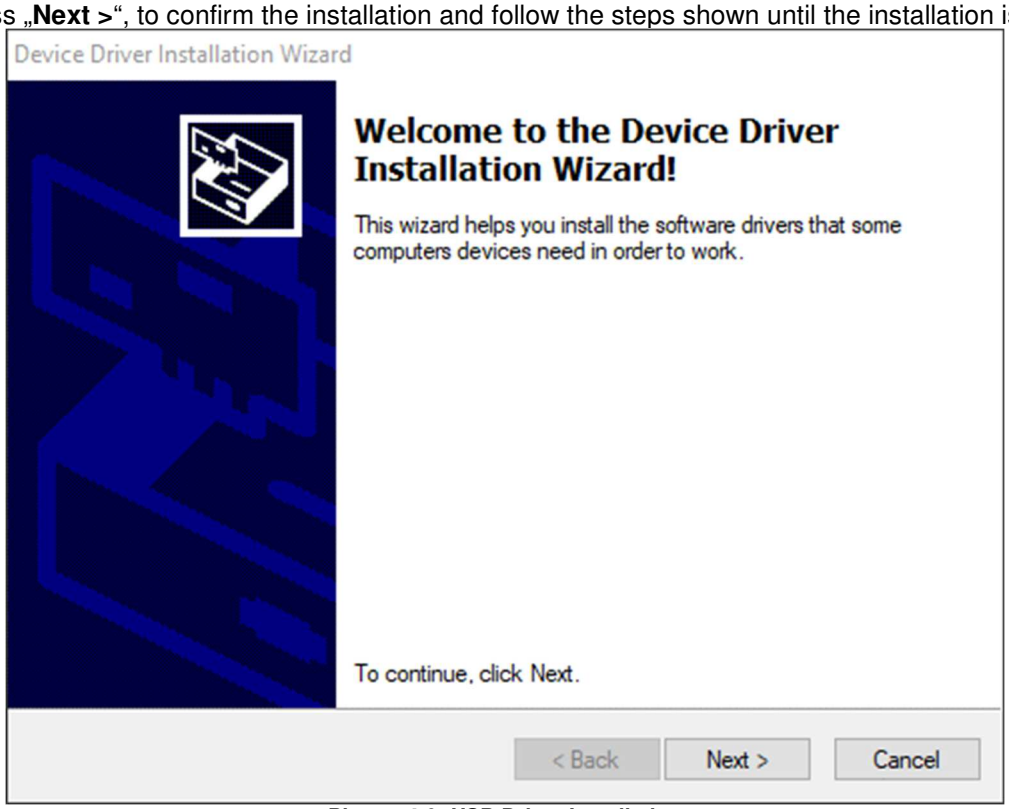
Picture 4-7: ABPMpro software installation

After the installation is ready the question of installing the USB drive will show up. Please check the box, (shown in the image below) highlighted with a red square. Then confirm with .



Picture 4-8: ABPMpro software installation

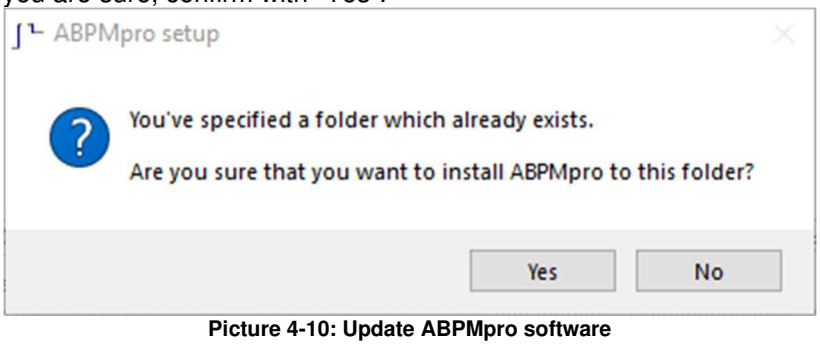
The installation of the USB driver will now start automatically.
Please press „**Next >**“, to confirm the installation and follow the steps shown until the installation is finished.



Picture 4-9: USB Driver Installation

4.3 Update from the software

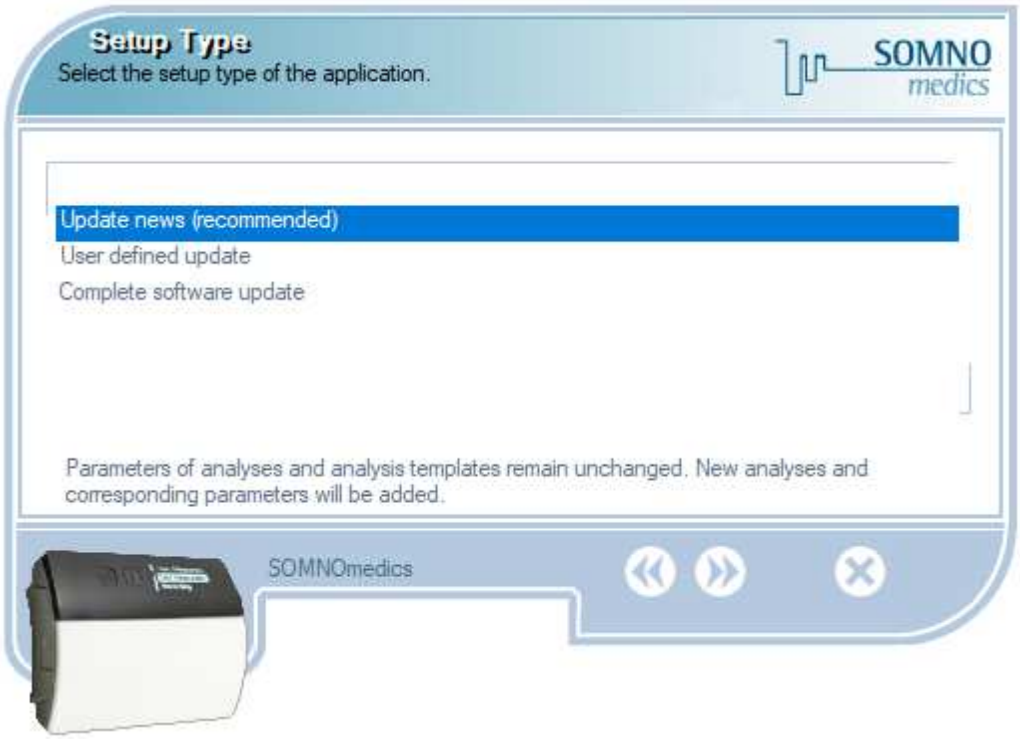
In our software, you will be automatically notified when an update is available.
If you would like to update the software, please install the software in the same folder as the current version has been installed.
You will be asked if you are sure, confirm with “Yes”.



Picture 4-10: Update ABPMpro software

Instead of new installation the following selection screen will appear, please select the desired option and confirm with  . The different options have the following meaning:

- **Update news (recommended)**: new analysis, channels and features of the software are updated. The settings of the analysis and the analysis templates remain as before;
- **User defined update**: you can choose which components shall be installed (Picture 4-12);
- **Complete software update**: all settings are overwritten with the new standard setting of the software.



Picture 4-11: Update ABPMpro software

Select which parts should be updated and confirm with .

Picture 4-12: User defined update ABPMpro software

No matter which option was selected, now follow the steps that are equal equivalent to the intial installation.

5 Operating the ABPMpro

During initialisation date and time of the ABPMpro is synchronised to the PC systems clock. Therefore it is important to have the correct date and time pre-set on the PC system. Please note that measurements running during the change of Summer/Wintertime will have a time shift.

The language on the ABPMpro will be synchronised to the ABPMpro software language on the PC system.

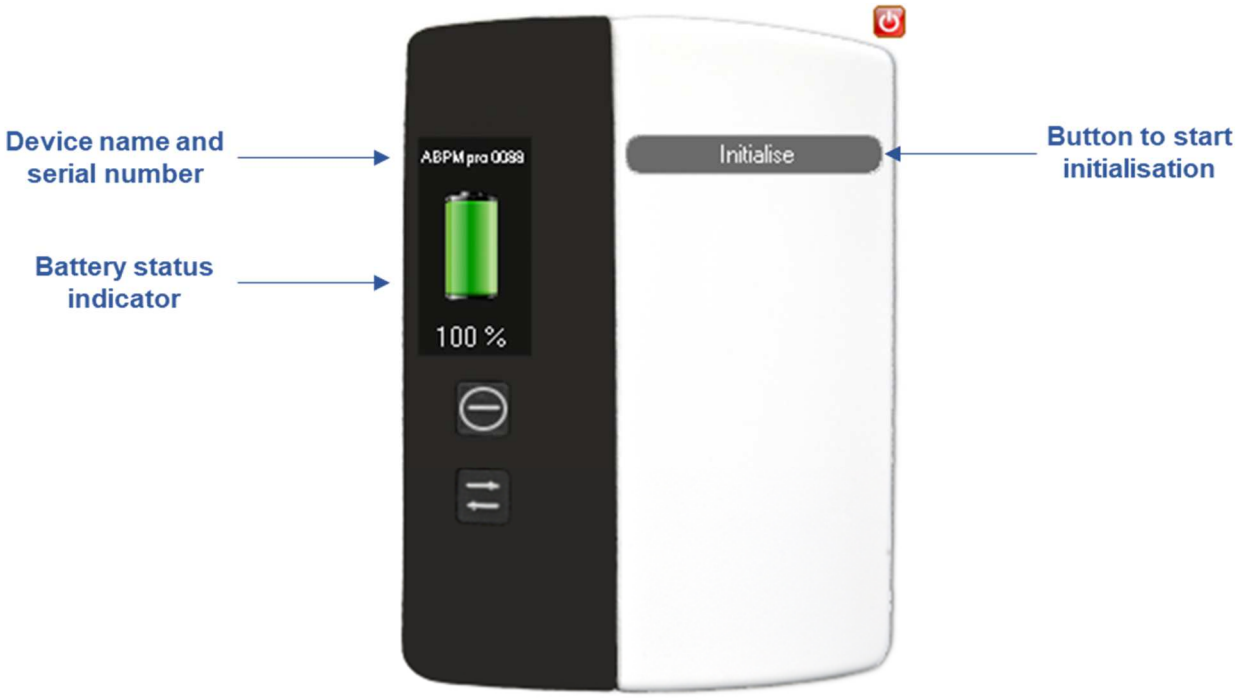
5.1 Initialisation

There are two ways to start a recording – where we recommend the first method:

1. Connect the ABPMpro to the PC and use the software;
2. Start a measurement on the device using the last programmed protocol.

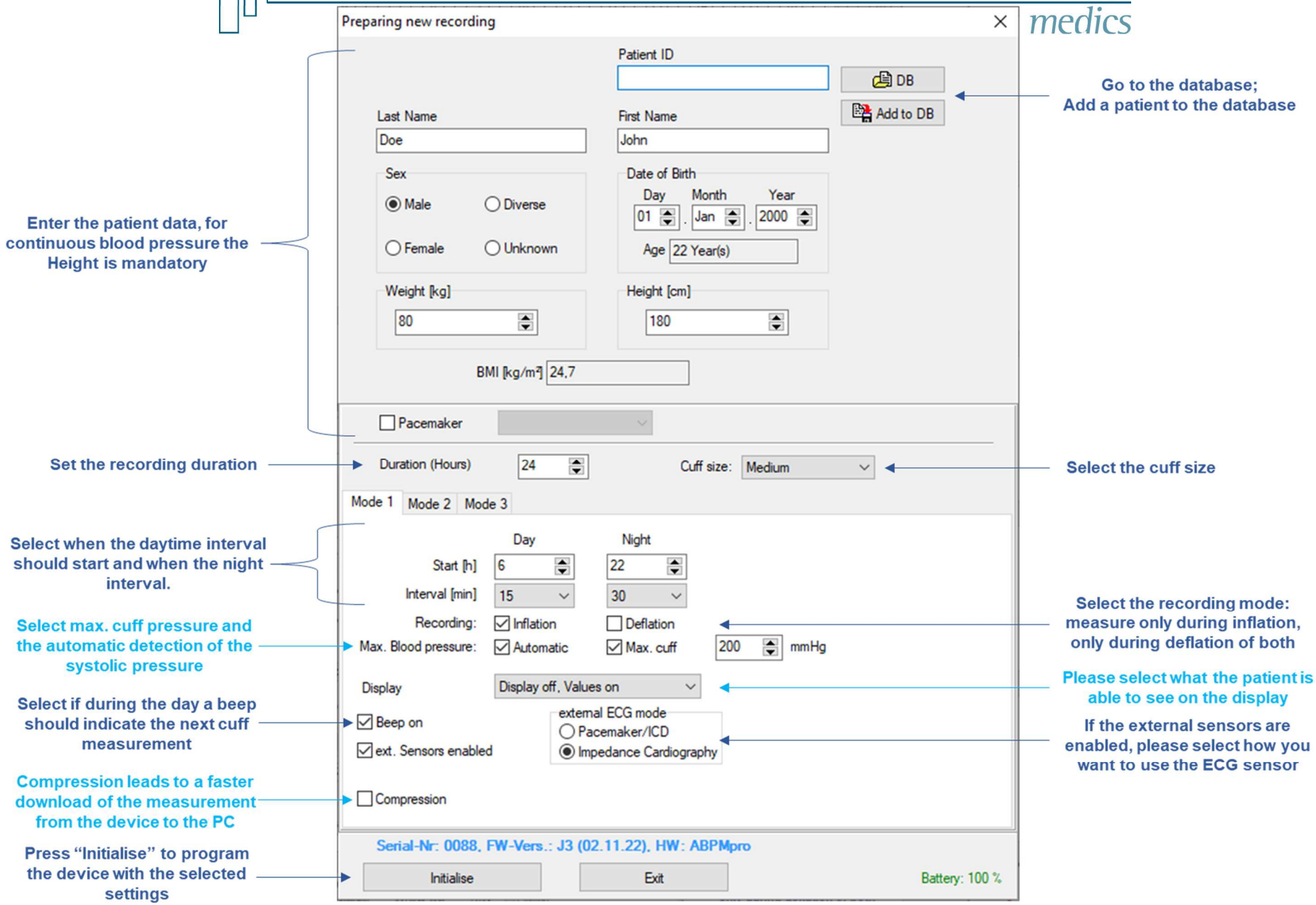
Initialisation Option 1 – using the PC

Connect the ABPMpro to the PC using the USB cable that has been supplied with the system and the virtual docking station should pop-up, as shown underneath.
In case it does not pop-up check chapter 7 for help with errors.



Picture 5-1: Virtual docking station

Please click the button “Initialise” to set a protocol for the next measurement.
The following window to prepare a new recording will appear.



Picture 5-2: Prepare new recording

Intervals
If you select “Off” during day and/or night interval, the device solely runs with the continuous blood pressure (the external ECG and pleth sensor are mandatory). If you select “Off” for both intervals the cuff will inflate at the very first measurement as this will be the calibration.

Max. blood pressure
The device will not inflate above the maximum set cuff pressure. If you have a patient with a higher blood pressure then please make sure to adapt this value or in case of children where you do not want to inflate too much, you can lower this value. The minimum value is 130mmHg.
In the automatic mode the systolic blood pressure is detected and ABPMpro will not pump unnecessary high.

Display
- Display off, values off: In this case the display will be off unless it is switch on by using the on button on the device. If in this case the display is on, there will only be two bars visible and no measurement values.
- Display off, values on: Same as above, but also the blood pressure values from the last measurement are visible.
- Display on, values on: This mode we do not suggest for long term recording as the display will be always on and the blood pressure values will also be shown.

External ECG mode
- Pacemaker/ICD is a pacemaker/ICD detection. The moment the pacemaker or ICD activates will be displayed in the ECG signal;
- Impedance Cardiography (ICG) – with this measurement we can provide the breathing frequency as well as the pre-ejection period that is part of our continuous blood pressure algorithm.

5.2 Application of the ABPMpro and its sensors

5.2.1 Applying the basic device

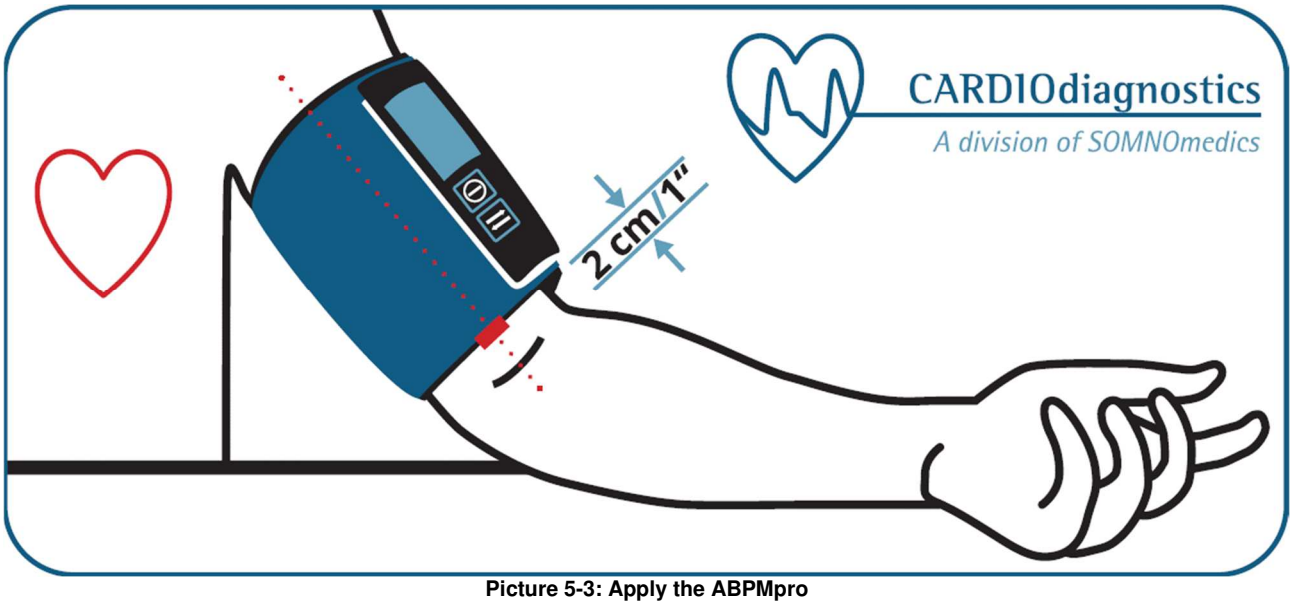
To apply the ABPMpro correctly, please follow these steps:

First measure the arm circumference with the supplied measuring tape. Measure the circumference at the middle of the upper arm.

Based on the circumference select the correct cuff size, see table below

Cuff Size	Article number	Arm circumference
Small	ABP500	18 – 24 cm
Medium	ABP501	24 – 34 cm
Large	ABP502	34 – 46 cm

Apply the cuff to the upper arm according to the picture below.
For a correct measurement, please ensure that the red stripe is on the artery as shown on the picture below.



Picture 5-3: Apply the ABPMpro

Slide the ABPMpro onto the docking station securely until you hear a click. Only then the device is properly attached.

If you do not have an external ECG sensor attached and would like to use the internal ECG sensor, make sure that both metal studs have skin contact. No skin preparation is needed, nor any conductive gel.

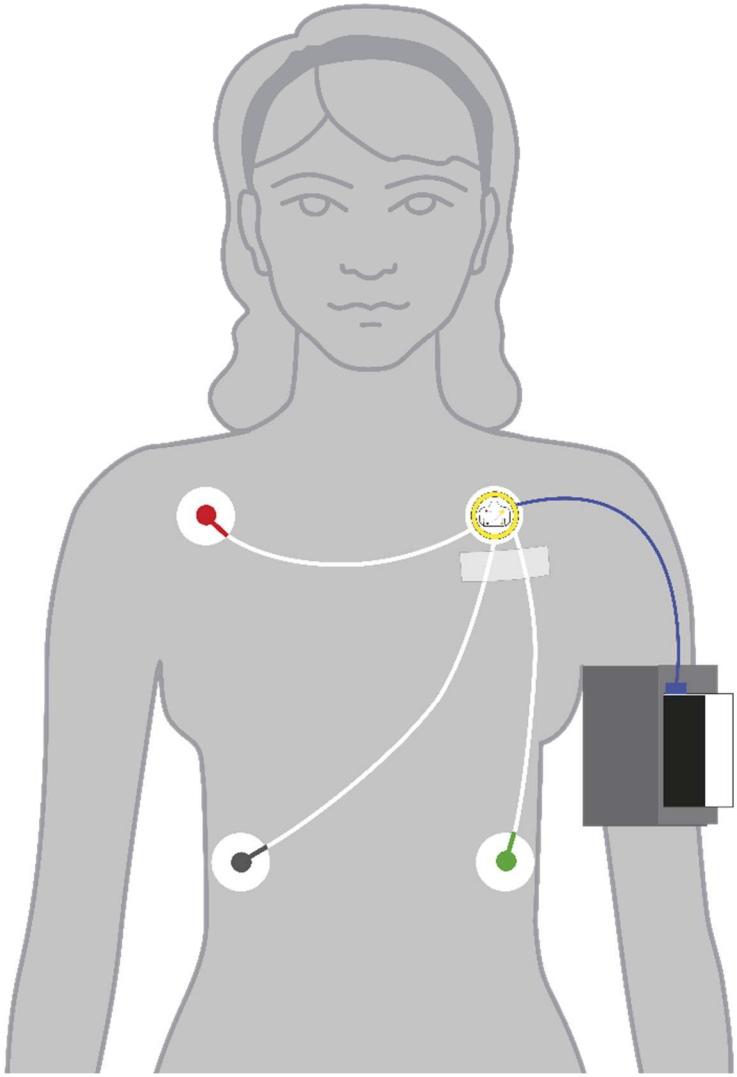
5.2.2 Applying the external ECG sensor

Make sure the skin is cleaned properly with an isopropanol where the ECG electrodes will be attached to the skin. In the case of the patient has a lot of chest hair on the places where the electrodes should be attached, we recommend that this is shaved.
Attached a disposable ECG electrode to each of the snap electrodes on the sensor.
Apply the electrodes to as displayed in the picture.
Please make sure that they are not attached on the clavicle as this will influence the signals.

The main part of the sensor (yellow) is the location of the integrated position sensor. To make sure the position is measured correctly, check that the sensor is in the upright position and cannot swivel or rotate during a measurement. To prevent this from happening you can use adhesive tape on one or more cables.

To reduce the risk of strangulation, especially in smaller patients, use adhesive tape to minimise movement of excess lengths of cable.

Attached the plug of the external ECG sensor to either one of the available ports (see picture 2-1). It could be that the ports are covered with blind plugs to prevent any dust and dirt getting into the ports.



Picture 5-4: external ECG application

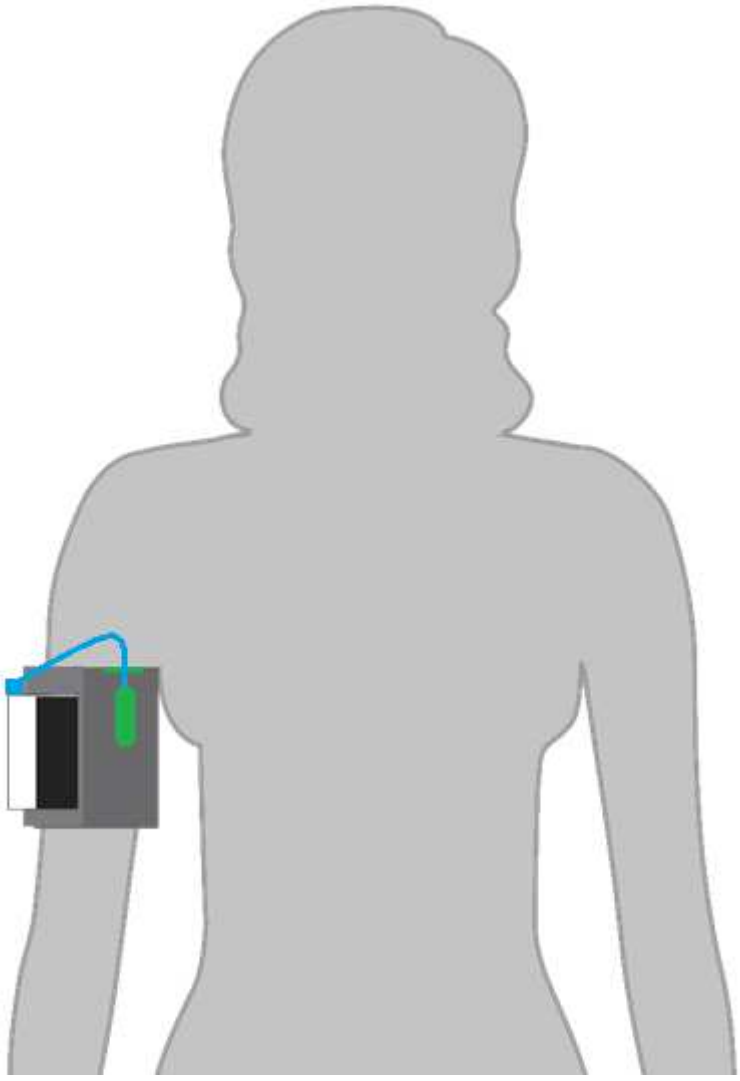
5.2.3 Applying the pleth sensor (ABP510 and ABP510R)

As a reference to apply the pleth sensor correctly you will find a green stripe on the cuff, which is when the cuff is properly attached, at the back of the arm.
The pleth sensor should be attached underneath the cuff at this point. Make sure the pleth sensor is completely underneath the cuff and the flat side of the sensor makes contact with the skin.

No skin preparation or conductive gel is needed.

To prevent the sensor from moving during the measurement we advise you to use a small strip of adhesive tape, to fix the sensor to the skin.

Attached the plug of the pleth sensor to either one of the available ports (see picture 2-1). It could be that the ports are covered with blind plugs to prevent any dust and dirt getting into the ports.



Picture 5-5: Pleth sensor application seen from the back

5.3 Starting the measurement

5.3.1 Precautions before starting a measurement

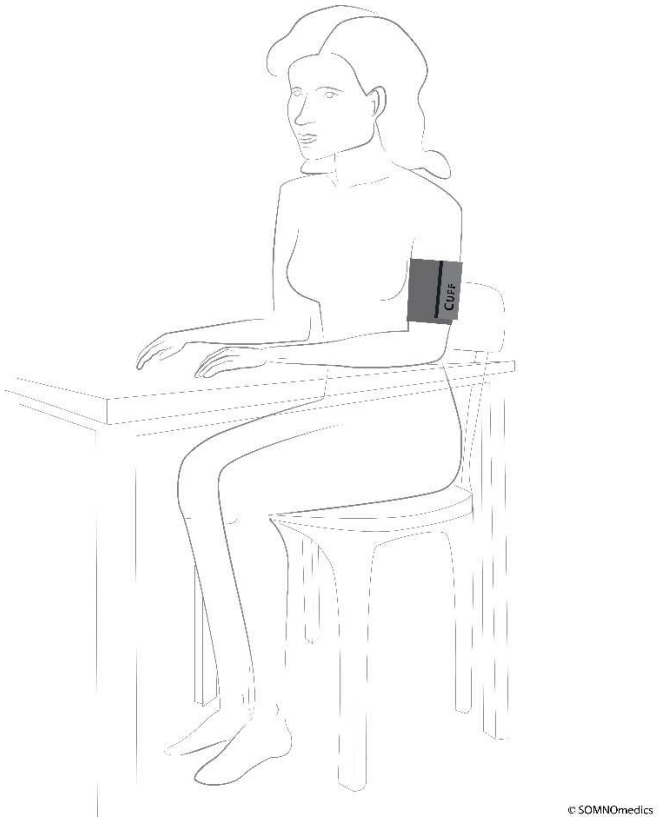
Make sure to follow underneath measurement procedure for the first measurement

Conditions

- Quiet room with comfortable temperature;
- No smoking, caffeine, food or exercise for 30 min before the measurement;
- Remain seated and relaxed for 3 – 5 minutes before starting the measurement;
- No talking by patient and/or staff during the measurement;

Posture

- Your patient sits comfortable and upright, feet placed side by side flat on the floor;
- The cuff around the arm, should be at the same level as your heart;
- The hand should be relaxed;
- Arm and/or hand should be supported as shown in the picture below.



Picture 5-6: Posture during the first measurement

The operator in the doctor's office will be beside the patient with the ability to read the values from the display. During the complete 24 hour measurement, the patient will be the operator and the device is worn on the upper arm of the patient.

Measurement

The first measurement should be successful (blood pressure values should be shown on the display), **otherwise the device will not start its programmed protocol**. If the measurement was not successful, please check the display error code with the codes mentioned in chapter 7 to see what you can do to prevent it from happening again. Then please repeat the above-mentioned procedure. If the measurement is successful, you can dismiss your patient.

If during initialisation the wrong cuff size was programmed it can be adapted on the device, please press the (arrow) button to move the cursor to the capital S, M or L. Use the (on) button to change the current selected cuff size. Use the arrow button to get back to the start recording.
In case the device noticed a different cuff size during the initial measurement, there will be an error message “cuff mismatch” the cuff size will be blinking. Please enter the correct cuff size and repeat the measurement procedure.

Picture 5-7: Cuff selection

Before starting a measurement, the device checks the battery charge. If this is no longer sufficient for the initialized measurement, a warning is displayed – to adapt the recording duration.

5.3.2 Starting a measurement

Switch the device on, by holding down the (on) button for three seconds. The logo will be displayed as well as the firmware version by showing the date of the firmware.
After that the underneath starting screen will be displayed.
Behind “Mode” like a news ticker the currently programmed protocol will be displayed.
Underneath the serial number, cuff size as well as the battery status are displayed.

Picture 5-8: Start recording

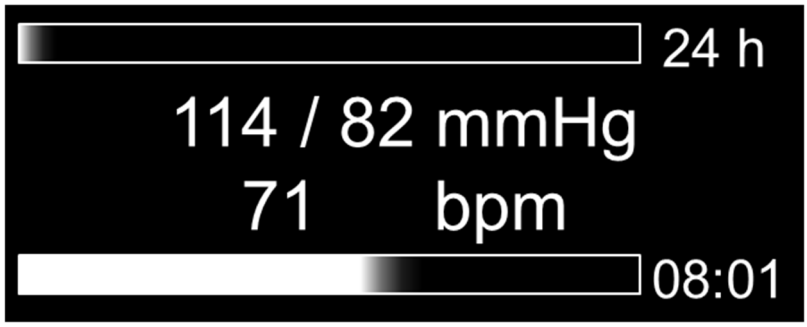
Confirm with the (on) button to start the recording. The device will now automatically search for attached sensors. Following this, the device automatically starts inflating the cuff. The inflation and deflation will be displayed in bars. No pressure is shown until the first measurement is finished.

As soon as the measurement is finished, the values are shown as well as a bar, showing the total planned recording duration. This bar will fill from left to right to display how much time has passed by.

Picture 5-9: Display after first successful measurement

If you want to cancel the recording use the (arrow) button to move the cursor to “Cancel“. Confirm with the (on) button to cancel the recording. You have to confirm this one more time. Then the measurement will be cancelled.

If the display off mode was selected, the display will switch off and the measurement will now follow it’s set protocol. In case the patient will switch on the device the following could be displayed.
Where the second bar will display the time interval until the next cuff inflation. This bar counts down.



Picture 5-10: Display off, values on mode

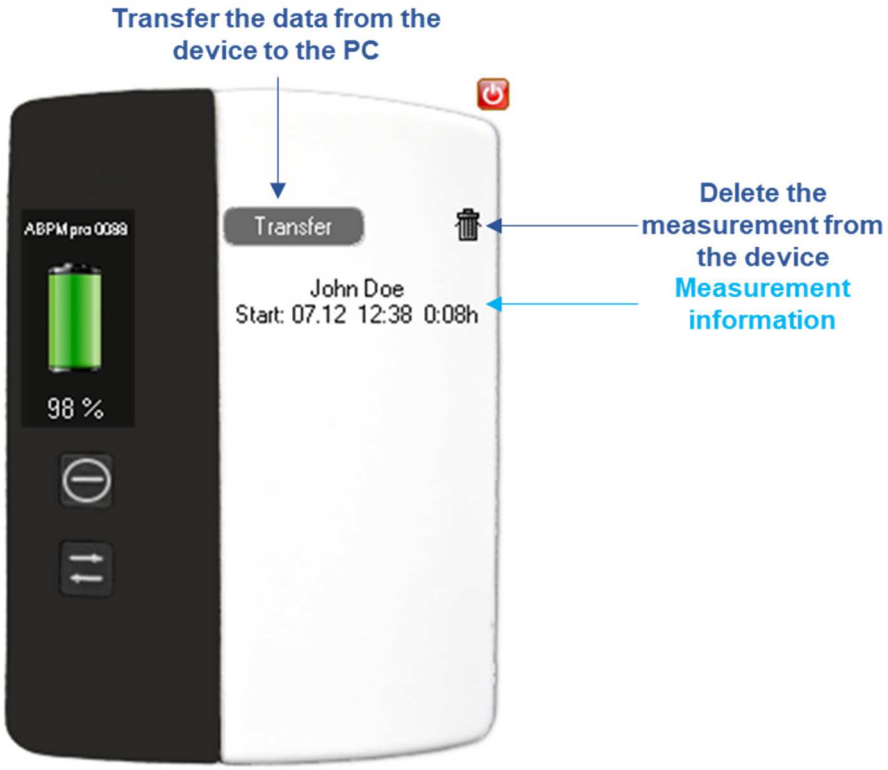
Picture 5-11: Display off, values off mode

During the measurement the patient can press the (arrow) button the place a patient marker. These will be recorded and displayed in the measurement. The device will make a short beep and the display will light up to indicate that the patient marker has been set.

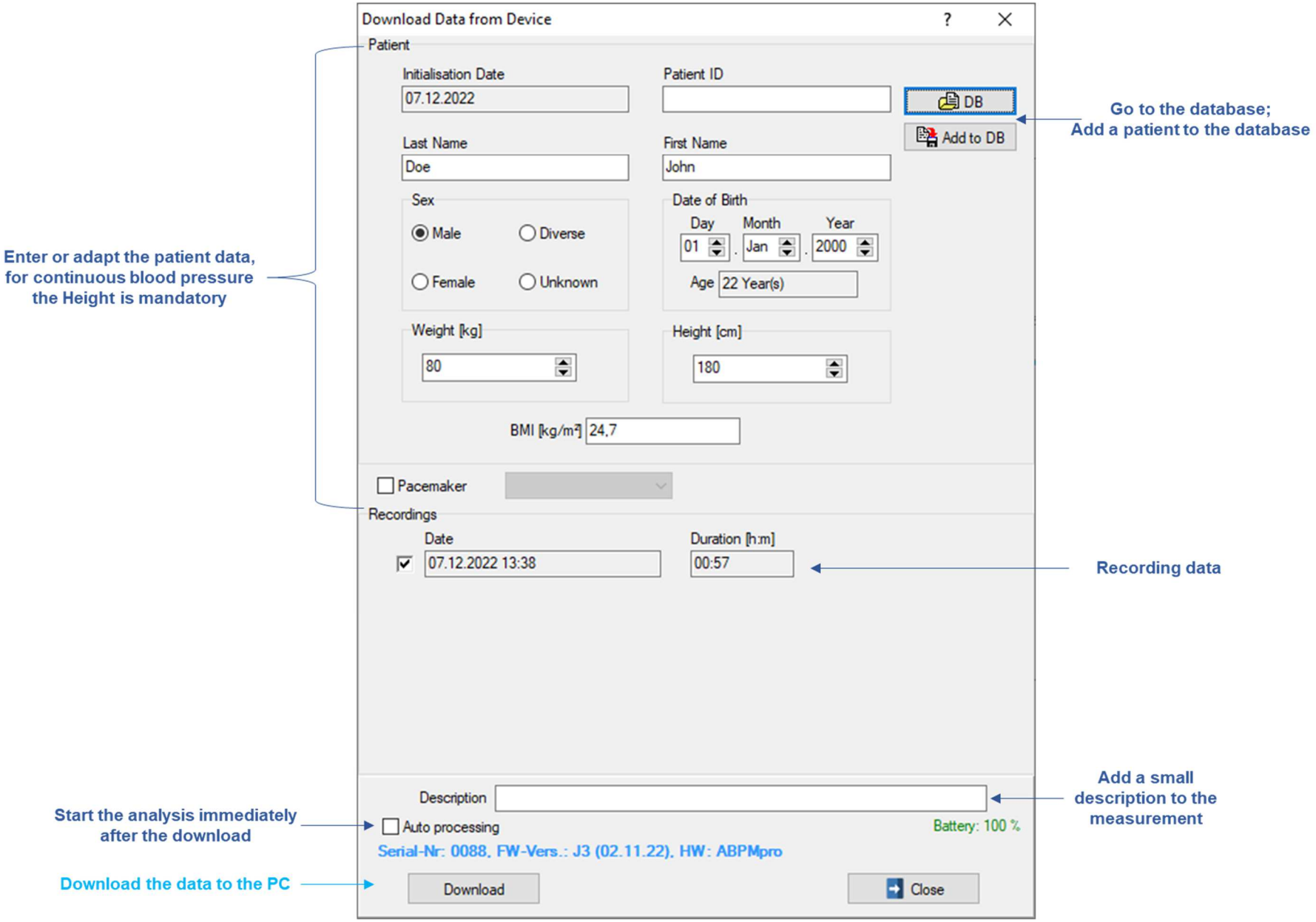
5.4 Transferring the data to the PC

To transfer the data from the ABPMpro, release the ABPMpro from the cuff.
Make sure the device and ECG sensor are no longer connected to the patient.
Now connect the ABPMpro using the USB cable to the PC.

The virtual docking station will appear as shown below.
If the device is connected to the PC and there is still a measurement running, it will automatically be stopped. It also cannot be restarted – a new measurement has to be restarted.



Picture 5-12: Transfer of the measurement



Picture 5-13: Download data to PC

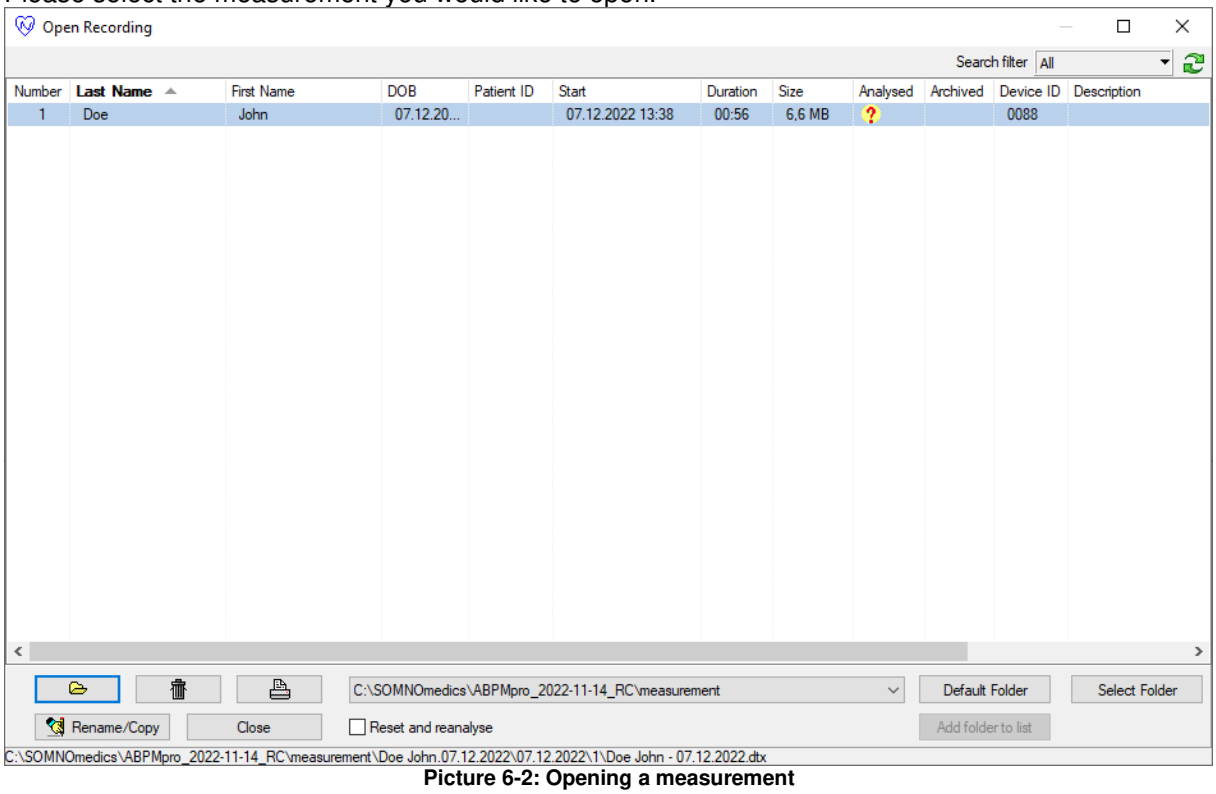
6 ABPMpro Software

To open the software please click on the icon shown underneath. This should be on your desktop.

Picture 6-1: Desktop icon ABPMpro software

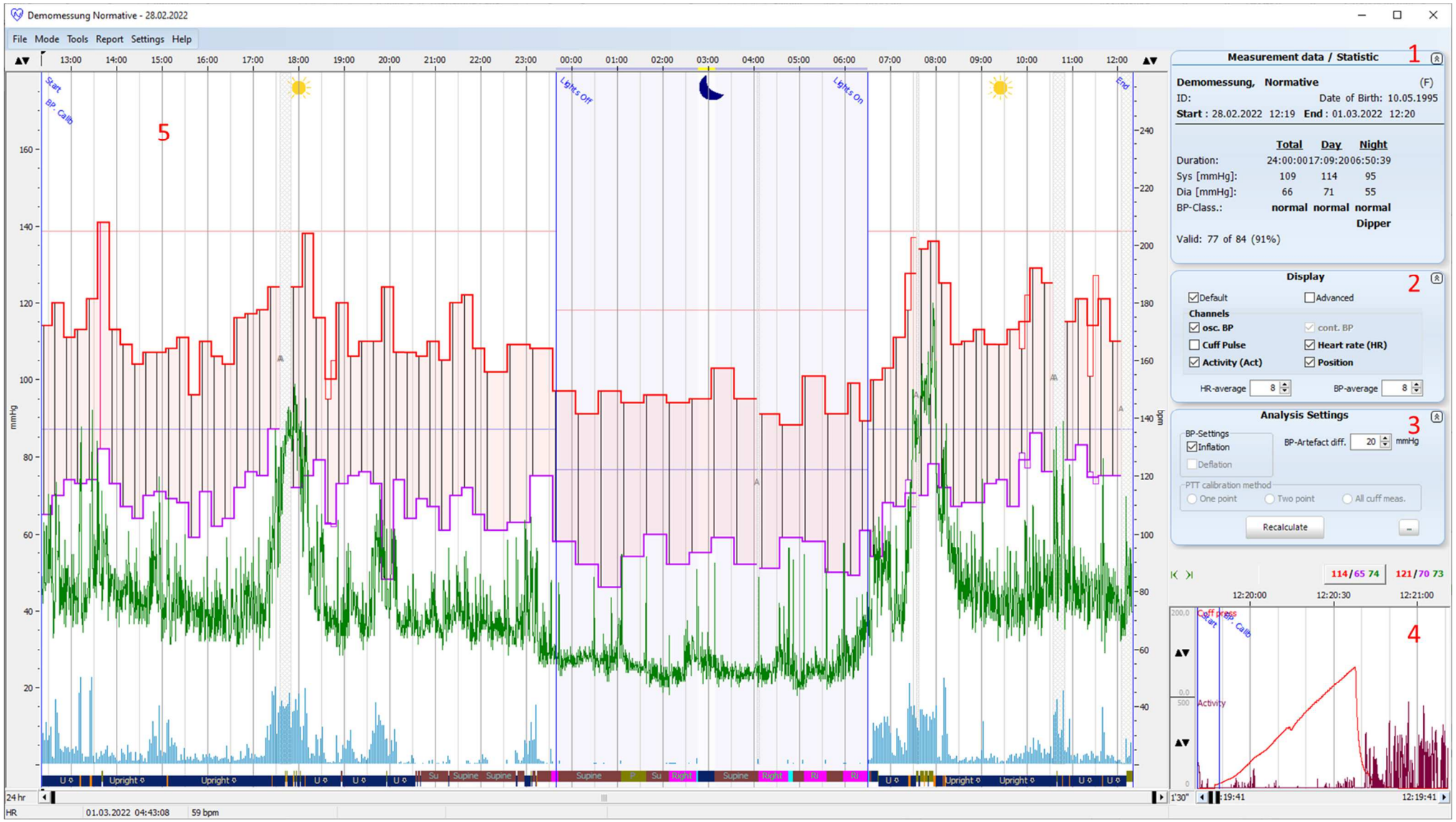
6.1 Opening a measurement

After opening the ABPMpro Software, the patient list will appear.
Please select the measurement you would like to open.



Picture 6-2: Opening a measurement

If the measurement has not yet beenanalysed, it will now be analysed automatically. In case “Auto processing” was selected during the transfer the measurement will be opened in the same status as shown below.

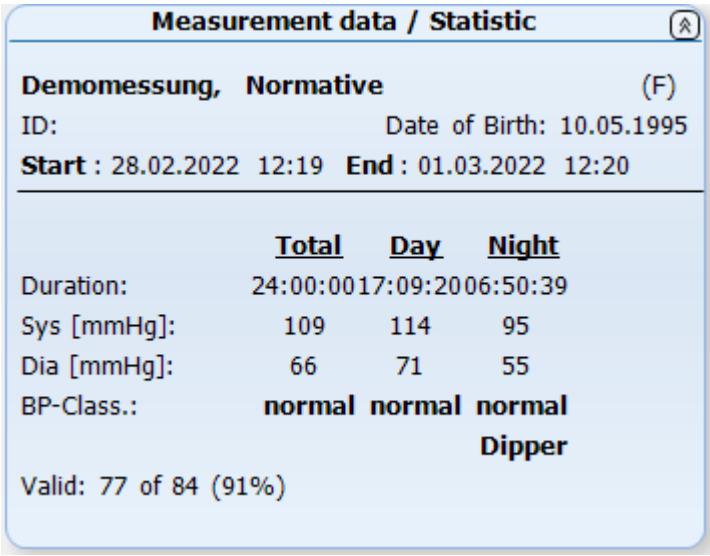


Picture 6-3: First view on a measurement

6.2 Adapting and analysing a measurement

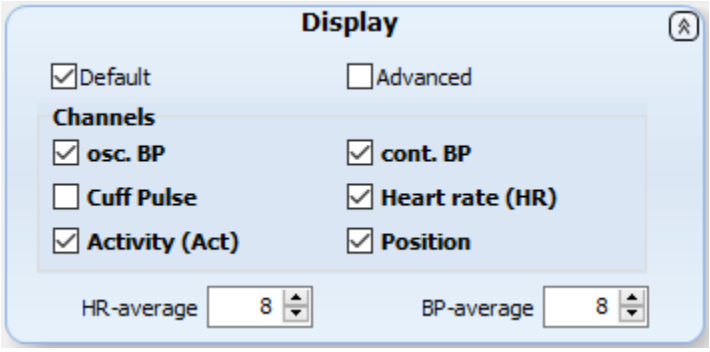
Please be aware that blood pressure readings can be affected by the measurement site, position of the patient (standing, sitting, lying down), exercise or the patient's physiologic condition. How to exclude a measurement is explained at point four in this chapter.

1. Measurement data / Statistic
By double clicking on thewindow shown below, you can adapt the patient data.
Displayed are also the cuff values as they will appears in the report.
Adapting the data will be mentioned at point 4 in this chapter.



Picture 6-4: Measurement data / Statistic

2. Display
Using the menu below lets you select which signal you want to see on the left side. As long as you stay in the „Default" mode. In the „Avanced" mode you have the opportunity to analyse all the raw data of the recorded signals. Since this is almost solely used in research we will not discuss this mode in the manual.
To adapt the selection of channels just simply check of uncheck a box and the display will be automatically updated.



Picture 6-5: Display settings

3. Analysis Settings
The averaging options are there to smooth both the continuous heartrate as well as the continuous blood pressure signal. Changing the value has an immediate effect on the displayed signals. It will not change the results in the report.

The window shown below demonstrates the adaptation of some settings.

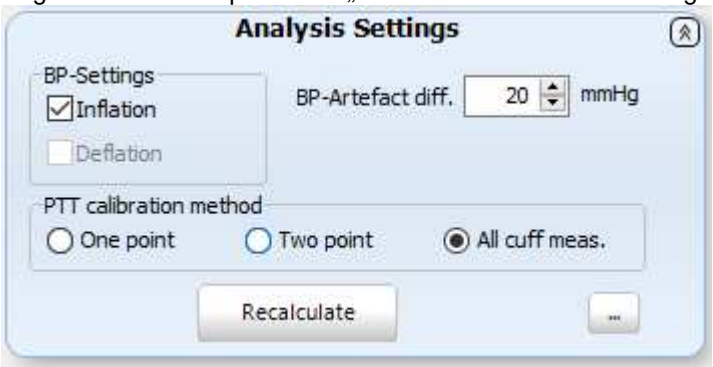
If both inflation and deflation was selected in the initialisation, then you can select according to which one you want to use to analyse the measurement: Inflation, Deflation or both.

The BP-Artefact diff. Is the minimum value that needs to be between the systolic and diastolic blood pressure. In the picture this is 20 mmHg. If the difference is smaller the software will define this as an artefact. If the difference is bigger the value will be measured displayed.

If you have measured a continuous blood pressure you can decide how often the continuous blood pressure has to be calibrated:

- One point – this will be the very first measurement made in the doctor's office;
- Two point – this will be the very first and last measurement done with the cuff;
- All Cuff meas. – each successful cuff measurement is a calibration point for the continuous blood pressure measurement.

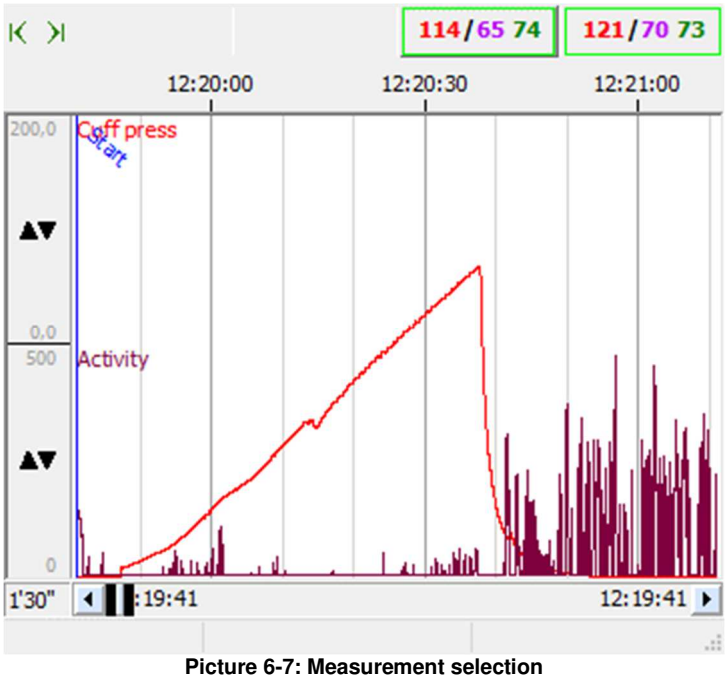
After adapting the settings make sure to press the „Recalculate" button to change the analysis.



Picture 6-6: Analysis settings

4. Check cuff measurement window

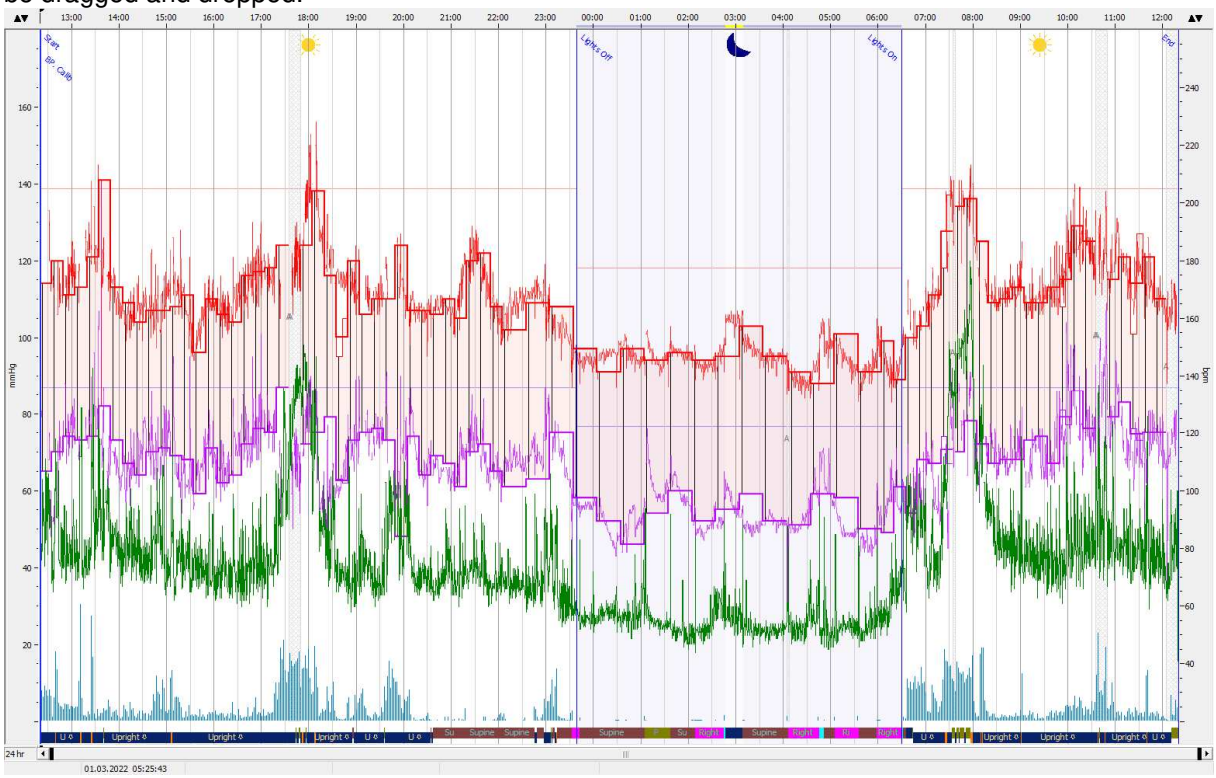
Excluding measurement values can be done via the window shown below, make sure the measurement is in Edit Mode (Menu: Mode > Edit Mode). If you want to exclude cuff based measurement values, you can delete them by giving a right click on the measurement value and choose for "Delete". If you want to restore a manually deleted measurement, right click on the measurement and choose for "„Restore".
Jump to the next cuff measurement using the arrows in the upper left corner of this window.



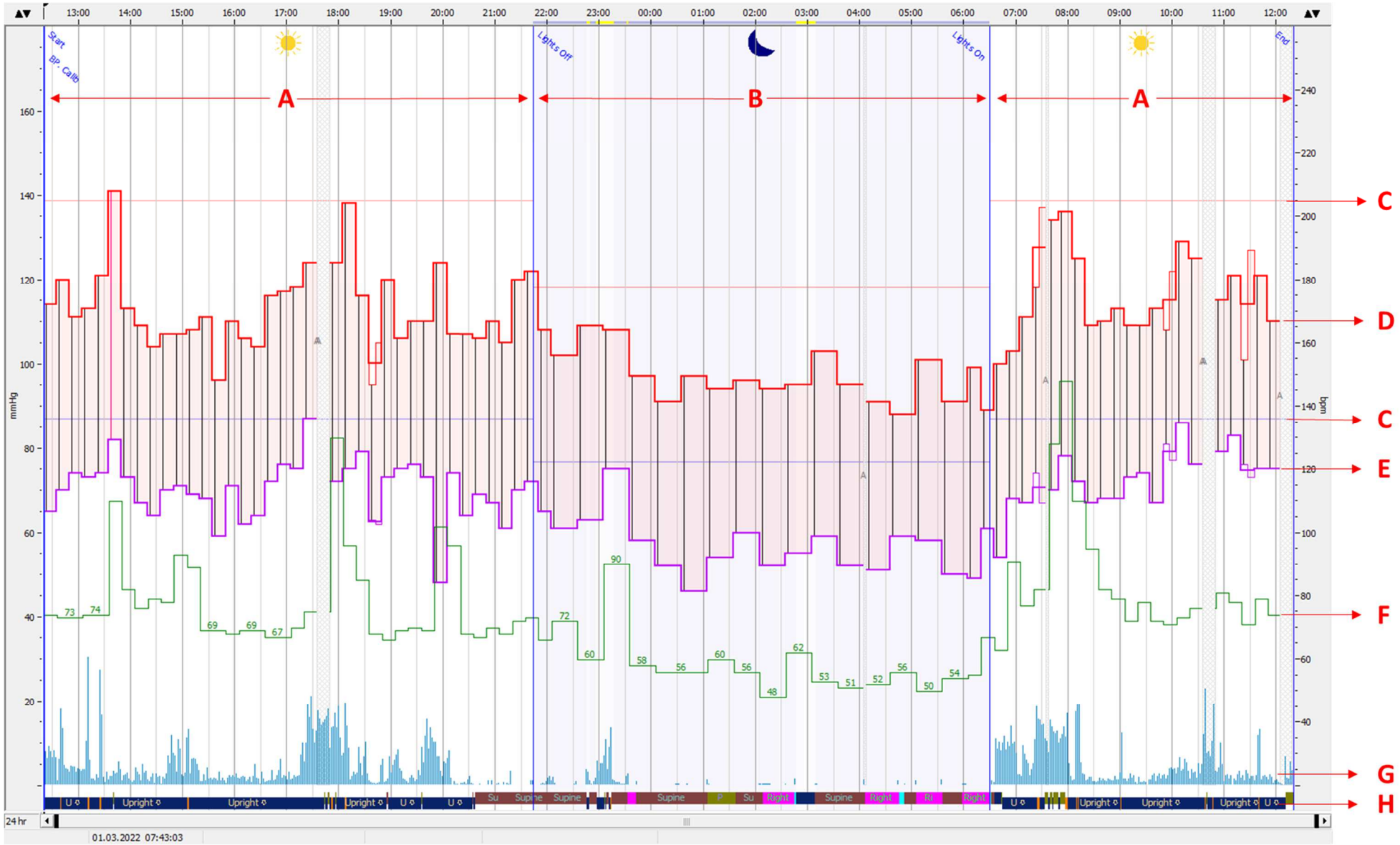
Picture 6-7: Measurement selection

5. Measurement overview window

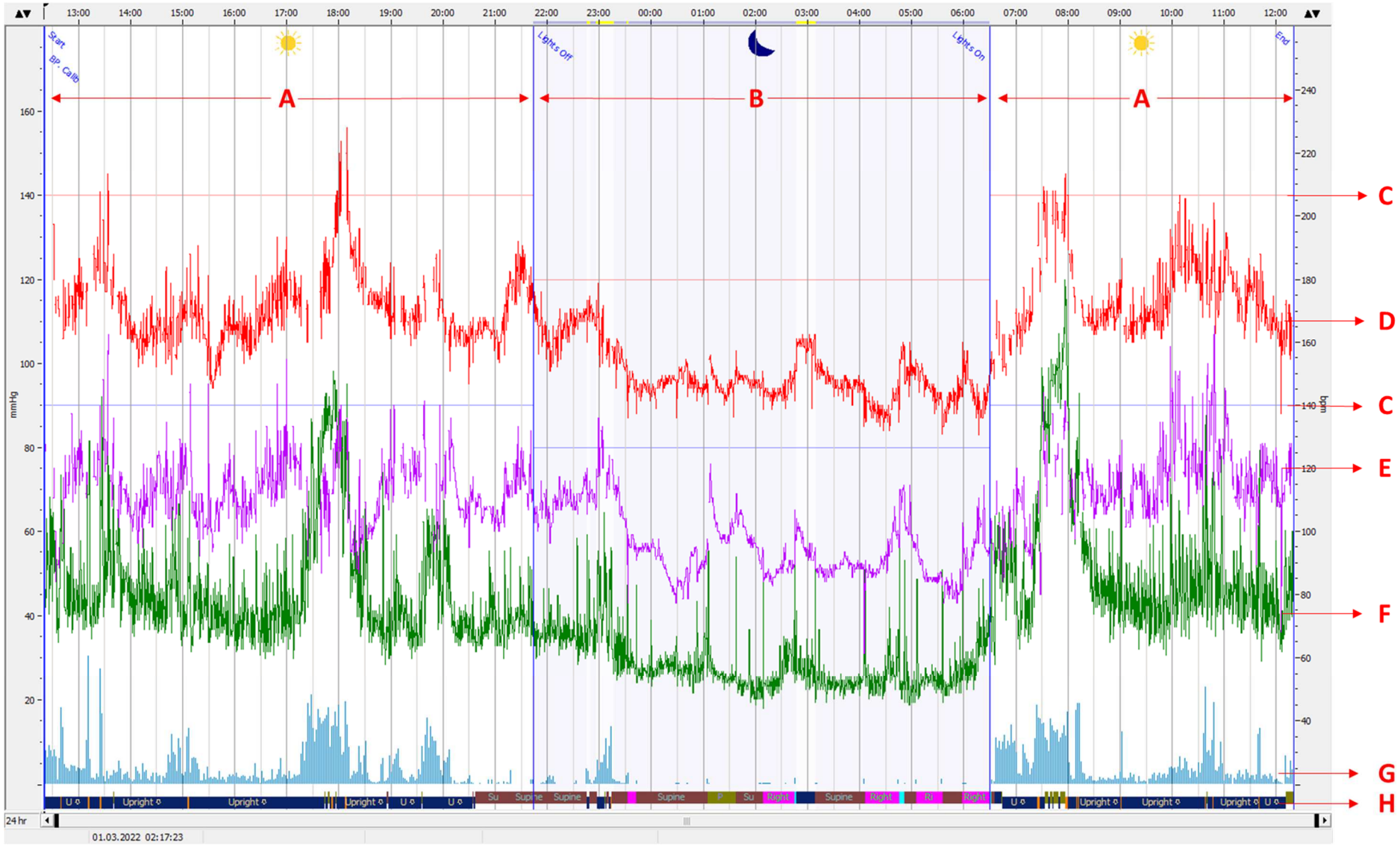
In the overview window, day and nighttime are marked with the sun and moon respectively.
The moon represents the time in bed (TIB). This time is automatically adjusted based on the body position and the activity. In case you would like to adapt it to a different timing. Make sure the measurement is in edit mode: Menu “Mode“ > Edit Mode. Move the mouse to the time bar and get close to the set marker. Now a small arrow should appear and the Lights off and on makers can easily be dragged and dropped.



Picture 6-8: Measurement overview



Picture 6-9: Measurement overview cuff-based blood pressure measurement



Picture 6-10: Measurement overview continuous blood pressure measurement

Explanation of what we see in two above shown overviews:

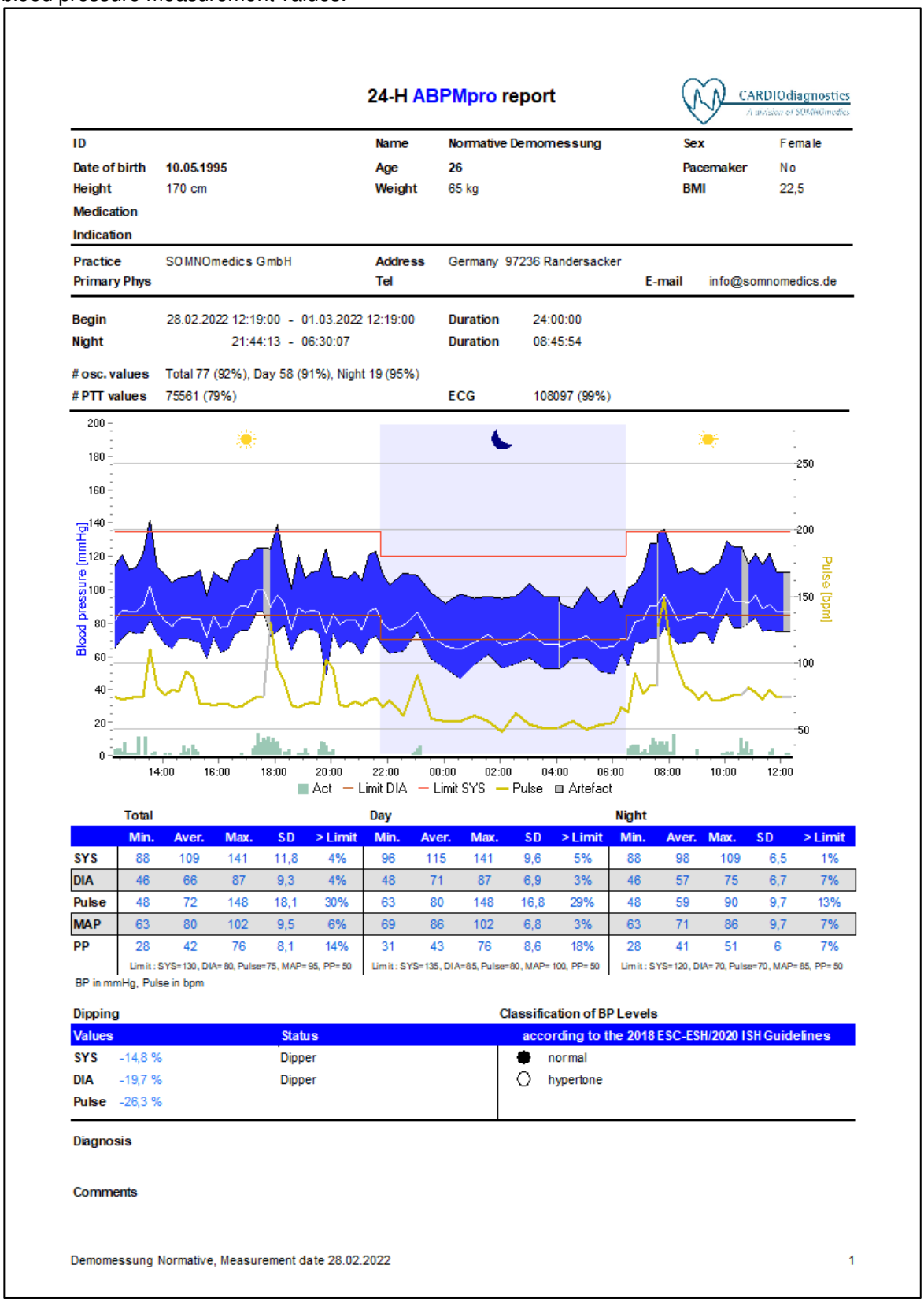
A. Daytime periods
B. Time in bed (TIB) period(s) marked by the lights off and on markers
C. Systolic (red) and diastolic (Lilac) limits for hypertension according to the set guidelines
D. Measured systolic values by the cuff in the upper window and continuous by Pulse Transit Time (PTT) in the lower window
E. Measured diastolic values by the cuff in the upper window and continuous by (PTT) in the lower window
F. Measured heart rate during the cuff measurement in the upper window, continuous in the lower window which can be plotted either by using the internal ECG or the external ECG sensor
G. Activity displayed by the blue bars – the higher the amplitude, the higher the activity was
H. Position, which also includes “walking”

Grey shaded areas also marked with a grey A in the middle of them are artefacts – the cuff-based measurement failed.

6.3 Generate a report

To generate a report, go to the Menu: Report. The report will be generated. This can be exported, by going though Menu: File > Export, in the following formats: pdf, rtf, docx and xlsx.

Underneath is a sample of the first page of the report, the graph and table displays only the cuff-based blood pressure measurement values.



24-H ABPMpro report

CARDIOdiagnostics
A division of SOMNOmedics

ID		Name	Normative Demomessung	Sex	Female
Date of birth	10.05.1995	Age	26	Pacemaker	No
Height	170 cm	Weight	65 kg	BMI	22,5
Medication					
Indication					
Practice	SOMNOmedics GmbH	Address	Germany 97236 Randersacker		
Primary Phys		Tel		E-mail	info@somnomedics.de
Begin	28.02.2022 12:19:00 - 01.03.2022 12:19:00	Duration	24:00:00		
Night	21:44:13 - 06:30:07	Duration	08:45:54		
# osc. values	Total 77 (92%), Day 58 (91%), Night 19 (95%)				
# PTT values	75561 (79%)	ECG	108097 (99%)		

	Total					Day					Night				
	Min.	Aver.	Max.	SD	> Limit	Min.	Aver.	Max.	SD	> Limit	Min.	Aver.	Max.	SD	> Limit
SYS	88	109	141	11,8	4%	96	115	141	9,6	5%	88	98	109	6,5	1%
DIA	46	66	87	9,3	4%	48	71	87	6,9	3%	46	57	75	6,7	7%
Pulse	48	72	148	18,1	30%	63	80	148	16,8	29%	48	59	90	9,7	13%
MAP	63	80	102	9,5	6%	69	86	102	6,8	3%	63	71	86	9,7	7%
PP	28	42	76	8,1	14%	31	43	76	8,6	18%	28	41	51	6	7%
	Limit : SYS=130, DIA=80, Pulse=75, MAP=95, PP=50					Limit : SYS=135, DIA=85, Pulse=80, MAP=100, PP=50					Limit : SYS=120, DIA=70, Pulse=70, MAP=85, PP=50				

BP in mmHg, Pulse in bpm

Dipping

Values		Status
SYS	-14,8 %	Dipper
DIA	-19,7 %	Dipper
Pulse	-26,3 %	

Classification of BP Levels

according to the 2018 ESC-ESH/2020 ISH Guidelines

- ● normal
- ○ hypertone

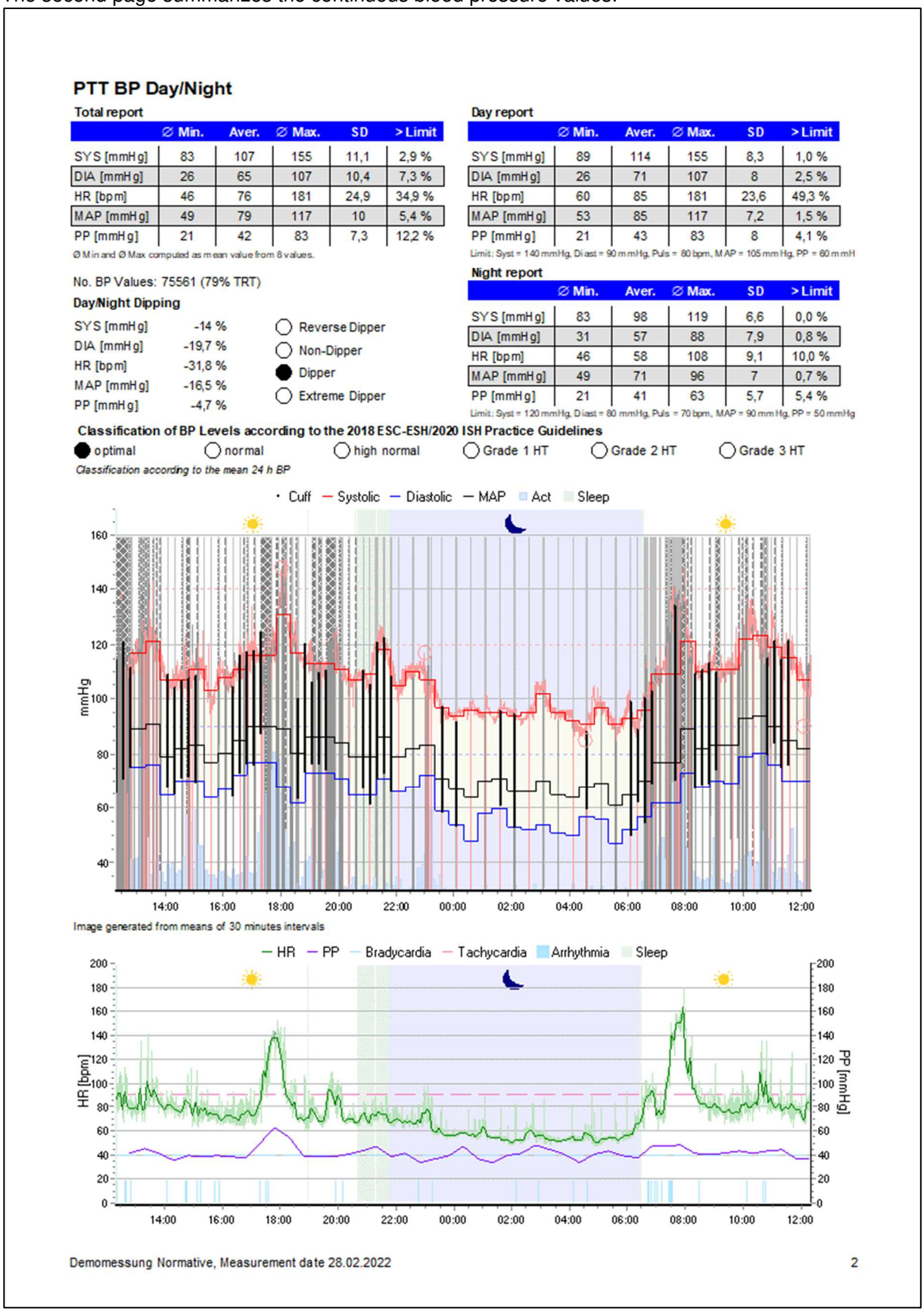
Diagnosis

Comments

Demomessung Normative, Measurement date 28.02.2022 1

Picture 6-11: First page report – cuff-based blood pressure measurement

The second page summarizes the continuous blood pressure values.



PTT BP Day/Night

Total report

	∅ Min.	Aver.	∅ Max.	SD	> Limit
SYS [mmHg]	83	107	155	11,1	2,9 %
DIA [mmHg]	26	65	107	10,4	7,3 %
HR [bpm]	46	76	181	24,9	34,9 %
MAP [mmHg]	49	79	117	10	5,4 %
PP [mmHg]	21	42	83	7,3	12,2 %

∅ Min and ∅ Max computed as mean value from 8 values.

No. BP Values: 75561 (79% TRT)

Day/Night Dipping

SYS [mmHg]	-14 %
DIA [mmHg]	-19,7 %
HR [bpm]	-31,8 %
MAP [mmHg]	-16,5 %
PP [mmHg]	-4,7 %

○ Reverse Dipper
○ Non-Dipper
● Dipper
○ Extreme Dipper

Day report

	∅ Min.	Aver.	∅ Max.	SD	> Limit
SYS [mmHg]	89	114	155	8,3	1,0 %
DIA [mmHg]	26	71	107	8	2,5 %
HR [bpm]	60	85	181	23,6	49,3 %
MAP [mmHg]	53	85	117	7,2	1,5 %
PP [mmHg]	21	43	83	8	4,1 %

Limit: Syst = 140 mmHg, Diast = 90 mmHg, Puls = 80 bpm, MAP = 105 mmHg, PP = 60 mmH

Night report

	∅ Min.	Aver.	∅ Max.	SD	> Limit
SYS [mmHg]	83	98	119	6,6	0,0 %
DIA [mmHg]	31	57	88	7,9	0,8 %
HR [bpm]	46	58	108	9,1	10,0 %
MAP [mmHg]	49	71	96	7	0,7 %
PP [mmHg]	21	41	63	5,7	5,4 %

Limit: Syst = 120 mmHg, Diast = 80 mmHg, Puls = 70 bpm, MAP = 90 mmHg, PP = 50 mmHg

Classification of BP Levels according to the 2018 ESC-ESH/2020 ISH Practice Guidelines

● optimal ○ normal ○ high normal ○ Grade 1 HT ○ Grade 2 HT ○ Grade 3 HT

Classification according to the mean 24 h BP

Image generated from means of 30 minutes intervals

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Picture 6-12: Second page report – continuous blood pressure measurement

Here the cuff based blood pressure values are plotted for the time intervals. Blueish background corresponds to the TIB.

Blood pressure table

Time	Sys [mmHg]	MAP [mmHg]	Dia [mmHg]	PP [mmHg]	Pulse [bpm]	Act [mg]
12:19:47	114	95	65	49	74	130
12:34:47	121	97	70	50	73	97
12:49:47	112	91	75	37	73	81
13:04:47	114	97	74	40	74	86
13:19:47	121	93	74	47	74	51
13:34:47	**142**	122	82	60	110	27
13:49:47	114	98	73	40	82	42
14:04:47	109	83	67	42	76	68
14:19:47	104	93	65	40	79	20
14:34:47	107	101	71	36	78	20
14:49:47	108	98	71	37	93	97
15:04:47	109	95	69	39	89	211
15:19:47	112	92	68	43	69	23
15:34:47	96	90	59	37	69	32
15:49:47	110	84	71	39	68	29
16:04:47	107	87	62	45	69	32
16:19:47	105	87	64	41	69	54
16:34:47	116	96	73	44	67	19
16:49:47	118	96	76	42	67	87
17:04:47	118	88	76	42	70	34
17:19:47	125	103	87	38	75	195
17:34:47	-	-	-	-	-	345
17:37:13	-	-	-	-	-	345
17:49:47	124	115	72	52	130	245
18:04:47	139	114	75	64	96	283
18:19:47	116	105	79	37	85	111
18:34:47	106	90	63	43	68	17
18:49:47	121	95	73	48	66	75
19:04:47	107	99	76	31	69	162
19:19:47	110	86	76	34	70	33
19:34:47	111	97	74	37	69	135
19:49:47	124	97	49	75	102	185
20:04:47	108	97	74	33	96	136
20:19:47	108	86	65	43	68	7
20:34:47	106	94	69	37	67	2
20:49:47	111	85	67	44	70	9
21:04:47	106	87	61	45	68	1
21:19:47	121	97	70	51	72	1
21:34:47	123	96	73	50	73	0
21:49:47	109	90	66	43	66	4
22:04:47	103	78	62	41	72	27
22:34:47	**110**	80	63	47	60	6
23:04:47	109	87	75	33	90	174
23:34:47	98	82	58	39	58	1
00:04:47	92	77	53	39	56	0
00:34:47	97	71	47	50	56	0
01:04:47	95	82	55	40	60	12

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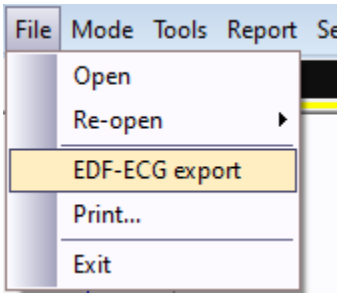
Picture 6-13: Third page report – cuff-based blood pressure table

6.4 ECG Analysis

The ABPMpro Software only has a limited ECG analysis function, which will be explain further down below.
For a complete ECG Analysis we recommend to use external ECG analysis software, like Cardiomatics. The data must be exported from our measurement to import it in the external ECG analysis software. Follow the steps displayed belowfor the export of the ECG signal from the ABPMpro Software, for the import in the external software we refer to the manual of the external software.

Go to file and select “EDF-ECG export”

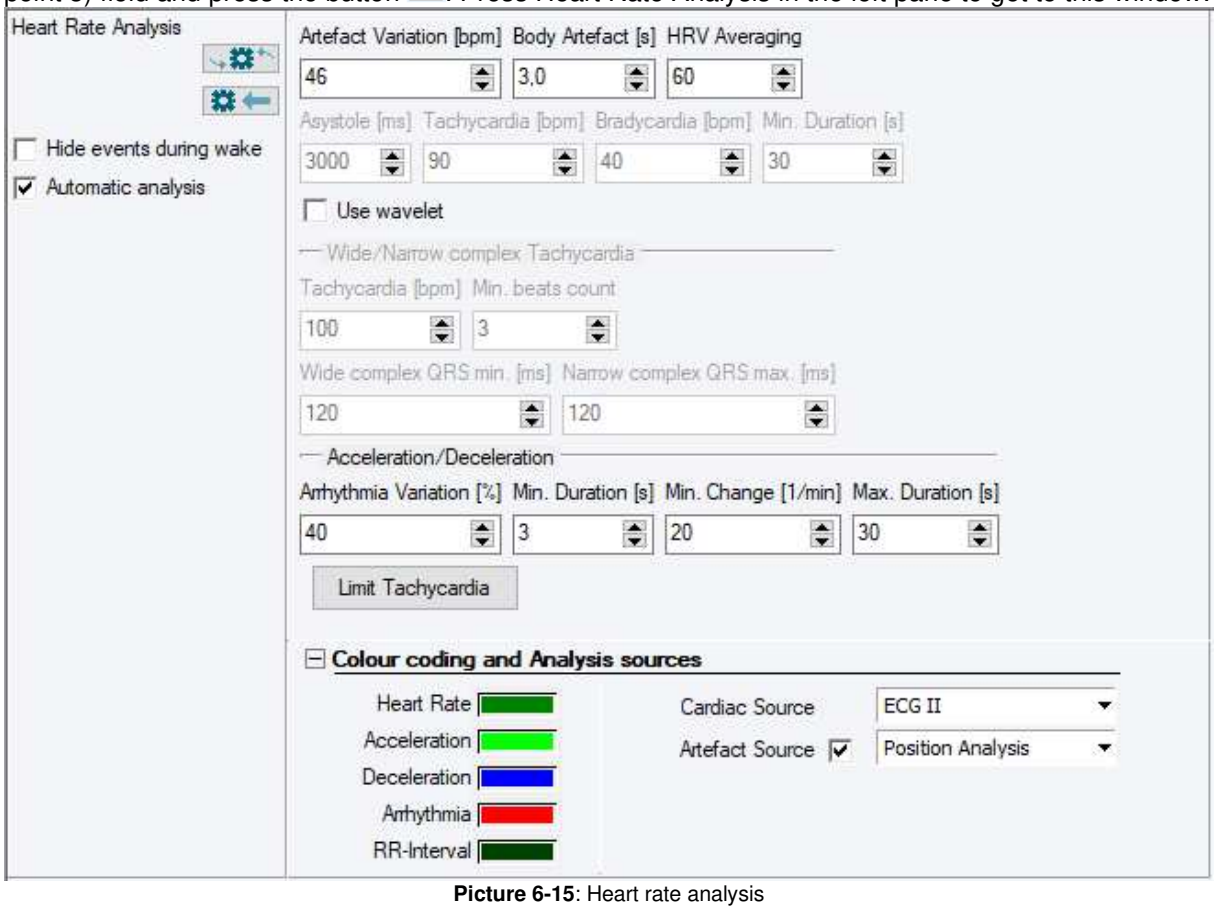


Picture 6-14: EDF-ECG Export

You will now be asked where to store the file make sure to use a location that you can easily find back as you need it again for the import of the data into the external software.
The data will be stored in EDF format and if you the external software accepts that format you can now import the ECG data into the external software according to their procedure.

6.4.1 Heart rate analysis

To adapt the source or settings for the heart rate analysis, go the “Analysis Settings” (Chapter 6.2 – point 3) field and press the button . Press Heart Rate Analysis in the left pane to get to this window:



Picture 6-15: Heart rate analysis

The calculation of the heart rate is based on the following algorithm „QRSDet“ from Hamilton, Tompkins, W. J., "Quantitative investigation of QRS detection rules using the MIT/BIH arrhythmia database", IEEE Trans. Biomed. Eng., BME-33, pp. 1158-1165, 1987, in der Version 12/04/2000.

The heart rate is calculated from the distance between two R-peaks. Using the following formula:

Heart rate = 60 / distance

Using the **Cardiac Source** field, the source can be selected on which the heart rate analysis is based.

7 Error messages and problem solving

Error description	Possible root cause	Check for root cause
Intialisation / Transfer		
Virtual docking station does not show up	Virtual docking station was closed	Go to the installation folder > bin64 > ABPMDockingStation.exe After the restart it should work again
Virtual docking station does not show up	Wrong USB cable	Please check that you use the original USB cable
Measurement duration too short		
Measurement duration is too short	The measurement was ended before duration end	Check in the logbook what happened. Go to the Menu: Tools > Info > Montage Check how the measurement was aborted
Measurement duration is too short	The measurement was ended before duration end	Check in the logbook what happened. Go to the Menu: Tools > Info > Logbook Check if the battery ran empty before the end of the measurement
Signals		
A signal was not recorded	The sensor was not attached before the measurement start or was broken	Check which sensors have been part of the measurement Go to the Menu: Tools > Info > Montage Check which signals have been recorded

Error messages

Error code	Message	Possible actions
E1	No pressure Check cuff	Please check if the cuff is applied correctly
E2	Cuff removed Check cuff	Please check if the cuff is applied correctly
E3	Time out Will be repeated	
E4	Movement Keep arm still	Please do not move during the cuff measurement
E5	No pulses Check cuff	No pulses have been detected please check how the cuff is applied
E6	Movement Keep arm still	Please do not move during the cuff measurement
E7	Movement Keep arm still	Please do not move during the cuff measurement
E8	No pulses Will be repeated	
E11	Movement Keep arm still	Please do not move during the cuff measurement
E12	Movement Keep arm still	Please do not move during the cuff measurement
E13	Leakage Check cuff	A leak was detected. Please check if the device was correctly attached to the cuff Please check if bladder has a leakage

E14	Movement Keep arm still	Please do not move during the cuff measurement

Failure messages

Error code	Message	Possible actions
F1	Sensor defect Please call service	Please contact your distributor
F2	External ECG defect Please call service	Please contact your distributor
F3	Pleth Please call service	Please contact your distributor
F4	Internal ECG Cuff securely fasten	Make sure the cuff is applied tight, so the internal ECG studs have skin contact
F5	Charge battery before measurement	The battery needs to be charged
F6	Defect pump Please call service	Please contact your distributor
F7	Defect motor Please call service	Please contact your distributor
F8	SD-card problem Please call service	Please contact your distributor
F10	Slow valve defect Please contact service	Please contact your distributor
F11	Fast valve defect Please contact service	Please contact your distributor
F12	Both valve defect Please call service	Please contact your distributor
F13	Leakage Please call service	Please contact your distributor
F14	RTC defect Please call service	Please contact your distributor
F15	SD card connection Please call service	Please contact your distributor

8 Maintenance and disinfection

8.1 Maintenance

The ABPMpro system requires maintenance every 2 years. The maintenance includes, calibration, internal battery exchange, examination for damage, a test for proper functioning and in case needed, a firmware update.

Maintenance can only be performed by the manufacturer or a certified professional by the manufacturer.

The calibration interval may be regulated by national laws or regulations differently in individual countries. Please check the regulations in your country.

8.2 Cleaning and disinfection

Disinfect the devices between each patient to prevent cross-contamination.

Object	Disinfectants (trade names)	**Concentration**	**Frequency**	**Miscellaneous**
ABPMpro ECG- Sensor Pleth-Sensor Cuff	wipe disinfection – tested: Terralin Liquid Mikrozid AF cloths	 ready for use ready for use	 After use	If necessary, remove adhesive residues. Follow the manufacturer's instructions!

The exposure time and dosage prescribed by the manufacturer of the disinfectant must be strictly observed.

An alternative disinfectant based on the ingredients can be: Wipe Out – Isopropyl Wipes.

This SOMNOmedics device complies with protection class IP 22 regarding ingression of humidity and water. Cleaning should be performed with a lint-free and damp cloth.

Ensure that no liquids seep into the device during cleaning.

The device and the sensors cannot be sterilized or autoclaved.

Special cleaning instructions for washing the cuff
Please be aware that using machine washing could deteriorate the cuff a lot faster compared to hand wash or above-mentioned cleaning.

In case you want to wash the cuff follow the steps down below:

1. Remove the bladder. The inside of the cuff consists of two fabric layers that overlap in the middle. This overlap allows the bladder to be inserted or removed in the cuff.
2. Close the Velcro and put the cuff in a wash bag
3. Wash the cuff at 30 ° C with a mild detergent. No dry cleaning, no bleaching, no tumble dryer, ironing with max. 100 ° C.
4. Let the cuff air dry. There must be no water left in the tubing of the docking station. Then insert the bladder back into the pocket provided.

Picture 8-1: Take bladder out of cuff

5. Perform a control measurement to verify that the device is ready for use.

8.3 Usage of the internal battery

The internal battery is a Lithium-Ion (Li ION) rechargeable battery. The battery offers a long life (approximately 500 charges), is not susceptible to memory effects and is ecologically friendly.

It takes approximately 2.5 h to charge a completely discharged battery. The battery is fully charged when the battery at the ABPMpro display is completely filled. To charge the ABPMpro use the supplied USB cable to either connect it to the PC or the power supply to charge the system without a PC.

In addition, the operating, storage and transport conditions of the basic device have to be observed as described in Chapter 0.

8.4 Essential requirements

In accordance with the IEC 80601-2-30 Ed. 2 standard, the following performance characteristics are defined:

- Limits of the error of the manometer 201.12.1.102
- Reproducibility of the blood pressure determination 201.12.1.107

These are subjected to the medical technical check (MTK) as part of the 2-year maintenance. This involves recalibrating the pressure sensor of the device and ensuring that the absolute pressure values are maintained.

In addition, the required essential performance characteristics according to IEC 60601-2-47:2012 for the automatic analyses, detailed in 201.12.1.101 and are fulfilled by third-party software corresponding to this standard. These include:

- Heart rate 201.12.1.101.3.1
- Supraventicular ectopy 201.12.1.101.3.2
- Venticular ectopy 201.12.1.101.3.3
- Bradycardia data 201.12.1.101.3.4
- Pauses 201.12.1.101.3.5
- ST segment shift 201.12.1.101.3.6
- ECG paper record 201.12.1.101.3.7

9 Service

9.1 Technical data ABPMpro

Signal	Resolution	Measurement interval	Frequency interval	Accuracy
Pressure	12 bit	0 – 300 mmHg	1000 Hz	1,5 %
ECG internal	16 bit		0,1 – 100 Hz	
ECG external	16 bit	±6 mV	0,03 – 150 Hz	±0,2 % + ±5 %
Pleth-Sensor	24 bit			
Body Position / Activity	12 bit	±4 G		±30 mg + 2 %/°C
Battery voltage	16 bit			±25 mV

Dimensions and weigth	125 g, 101 x 75 x 25 mm
Data processing	Active filtering of the signals
Power supply Akku	Dimensions: 60 x 25 x 11 mm Nominal voltage: 3,7 V Maximum charging voltage: 4,2 V Rated capacity: 1800 mAh Maximum charging current: 1,5 A Integrated protection circuit with overcharge protection with 4.2 V, deep discharge protection at 2.8V The service life is 15 months of operation or about 500 charging cycles. The battery is permanently installed and cannot be replaced**!**

Power supply ABPMpro (ABP530)

Input	100 – 240 V ~50 – 60 Hz 0,32 – 0,19 A
Output	5,1 VDC 2,4 A
Protection class	II

9.2 Life time

The assumed product life for the ABPMpro is 7 years.

We therefore strongly recommend that you follow the recommended maintenance intervals of 2 years. Otherwise, we cannot guarantee the expected product life cycle.

Prematurely aged or defective sensors and connecting cables must be replaced.

9.3 Operating, storage and transport conditions

Store the device and accessories in the supplied transport bag. This protects the device from dust, lint, light and pests.

Humidity	During operation: 15 % – 90 %, non-condensing. During storage/transport: 20 % – 95 %, non-condensing
Environmental temperature	During operation: +5 °C – +40 °C During storage/transport: -20 °C – +70 °C
Atmospheric pressure	700 hPa – 1060 hPa

Products are to be packed for transport in package that have enough shock absorbing materials. All packed and shipped in a suitable transport carton. Transport and delivery are carried out by service personnel or distributors.

The device must be protected from penetrating water and moisture. The device must not be used in an oxygen-enriched environment.

From the minimum storage temperature to operation, the device should be warmed up for one hour at an ambient temperature of 20°C.
From the maximum storage temperature to operation, the device should be cooled down for half an hour at an ambient temperature of 20°C.
Care should be taken to avoid condensation.

9.4 EMC information

Refer to the tables in this section for specific device information for compliance with IEC60601-1-2 standards.

This information is excerpted from European standards for electrical medical devices. They must be observed when installing and combining SOMNOmedics devices with products from other manufacturers. In case of ambiguity, the complete standard should be consulted.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emission CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2 (*)	N/A	Only for devices with power consumption >75 W
Voltage fluctuation/flicker IEC 61000-3-3 (*)	N/A	

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Immunity test	**IEC 60601- Test Level**	**Electromagnetic environment– guidance**
Electrostatic discharge (ESD), IEC61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient /burst, IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment. Input/ Output nicht anwendbar. Alle Kabel sind kürzer als 3m.

Surge, IEC 61000-4-5	± 0,5 kV, ±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. Common mode nicht anwendbar. Netzteil Schutzklasse II
Voltage dips, short interruptions and voltage variations on power, IEC 61000-4-11	0 % U_τ for ½ cycle at 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_τ for 1 cycle at 0 degree 70% U_τ for 25 / 30 cycles at 0 degree 0 % U_τ for 250 / 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery. Note: $U\tau$ is the a.c. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	30 A/m	Power frequency and magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
		Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V / 6 V for ISM- and amateur radio frequency bands 150 kHz to 80 MHz 80 % AM @t 2 Hz	$d=1,2\sqrt{P}$
Radiated RF, IEC 61000-4-3	10 V/m, 80 MHz to 2,7 GHz, 80 % AM @ 2 Hz	$d=1,2\sqrt{P}$ for 80 MHz to 800 MHz $d=2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
Proximity Field from Wireless Transmitters, IEC 61000-4-3	385 MHz PM @ 18 Hz, 27 V/m 450 MHz FM ± 5 kHz @ 1 kHz, 28 V/m 710 MHz PM @ 217 Hz, 9 V/m 745 MHz PM @ 217 Hz, 9 V/m 780 MHz PM @ 217 Hz, 9 V/m 810 MHz PM @ 18 Hz, 28 V/m 870 MHz PM @ 18 Hz, 28 V/m 930 MHz PM @ 18 Hz, 28 V/m 1720 MHz PM @ 217 Hz, 28 V/m 1845 MHz PM @ 217 Hz, 28 V/m 1970 MHz PM @ 217 Hz, 28 V/m 2450 MHz PM @ 217 Hz, 28 V/m 3500 MHz PM @ 217 Hz, 28 V/m 3700 MHz PM @ 217 Hz, 28 V/m 5240 MHz PM @ 217 Hz, 9 V/m 5500 MHz PM @ 217 Hz, 9 V/m 5785 MHz PM @ 217 Hz, 9 V/m	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ABPMpro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
		The field strengths outside shielded stationary RF transmitters determined by an on-site electromagnetic examination should be less than 3 V / m. Faults may occur near devices marked with the following symbol: 

9.5 Malfunction

If safe and proper operation is no longer possible, the device must not be operated anymore and securely stored to prevent inadvertent operation and injury.
This applies:

- if the device is visibly damaged (broken housing)
- if the device is no longer functional (incorrect measurement results)
- if parts of the device are loose
- if connectors are damaged (damaged cables)

In such a case use our telephone service! We assure you fast and competent advice and processing. Our contact information can be found in chapter 1.

9.6 Warranty

Warranty of security, reliability and functionality of the device is only provided by SOMNOmedics if:

- add-ons, modifications and repairs are carried out exclusively by persons authorised by SOMNOmedics or made by SOMNOmedics personnel.
- the device is only handled by instructed persons and skilled workers.
- transportation of the device is only carried out with original packing.
- the operation site complies with the ambient conditions of the device.
- the device is used according to the instruction manual (consider the safety instructions)

The warranty only refers to the main device ABPMpro and includes a period of 24 months.

If you use accessories which are not authorised by SOMNOmedics and it comes to service provision, this will be invoiced.

It is not permitted to open the device. Repairs, opening the device and modifications are carried out exclusively by our authorised service partners or SOMNOmedics.

9.7 Disposal of application parts and/or the ABPMpro

Used or replaced parts are not to be disposed of in the household waste.
Please consider the regional environmental regulations regarding disposal of used electronic devices and electronic parts.
Patient data saved on the memory card of the main device must be deleted for data protection reasons.

Note: Since October 1, 1998, portable batteries may no longer be disposed of in household waste after consumption. The consumer is obliged to return used batteries to the manufacturer, to the retailer or to a municipal collection point.

9.8 Accessories and spare parts

Part number	Description	Cable length	Part of part number
ABP050	ABPMpro	-	●
ABP500	Cuff - Small	-	○
ABP501	Cuff – Medium	-	●
ABP502	Cuff - Large	-	○
ABP530	Power supply	-	●
BT-K0000502	USB-charging cable	150 cm	●
ABP520	3-channel-ECG-Sensor	Sensor cable: 50 cm Green electrode: 35 cm Red electrode: 35 cm Black electrode: 50cm	○
ABP510	Plethsensor continous cuffless blood pressure	20 cm	○
ABP510R	Plethsensor cuffless blood pressure	20 cm	○
SEN030	Nuprep cleanser	-	○
SEN006	Push button electrodes	-	○

● Included
○ optional

9.9 Notes