User manual

Version 2017-03-10

PHYSIO-PORT

Ambulatory Blood Pressure System

PAR Medizintechnik GmbH & Co. KG
Sachsendamm 6
10829 Berlin
Germany

Tel.: +49 30/ 2350700
Fax: +49 30/2138542
E-Mail: info@par-berlin.com
Web: http: www.par-berlin.com

CE - 0482

Printed in Germany

Contents

1. GENERAL INFORMATION ..... - 6 -

1.1 To this manual ..... - 6 -

1.2 Confirmity ..... - 6 -

1.3 Identifier ..... - 6 -

2. INTENDED USE: ..... - 8 -

2.1 Oscillometric Measurement Method ..... - 8 -

2.2 Biocompatibility ..... - 9 -

2.3 Standards ..... - 9 -

3. SAFETY INSTRUCTION AN USE ..... - 10 -

4. PHYSIO-PORT RECORDER ..... - 11 -

4.1 Operations controls ..... - 11 -

4.2 Button functions ..... - 12 -

4.3 LCD display ..... - 13 -
4.3.1 Displayed symbols ..... - 13 -
4.3.2 Time display ..... - 13 -
4.3.3 Functional control ..... - 13 -

4.4 Power supply ..... - 15 -
4.4.1 General ..... - 15 -
4.4.2 Inserting batteries ..... - 15 -

4.5 PHYSIO-PORT Cuffs ..... - 16 -

4.6 Connections ..... - 16 -
4.6.1 Connection of the cuff to the recorder ..... - 16 -
4.6.2 The connection cable to the recorder ..... - 16 -

5. SOFTWARE INSTALLATION ..... - 17 -

5.1 PC software Physioportwin ..... - 17 -

5.2 Settings ..... - 19 -
5.2.1 System ..... - 20 -
5.2.2 GDT interface ..... - 21 -
5.2.3 Print/Export ..... - 24 -
5.2.4 Parameter ..... - 26 -

5.3 Network Installation ..... - 27 -

6. COMMENCING LONG TERM BLOOD PRESSURE MEASUREMENT ..... - 28 -

6.1 Connecting the recorder ..... - 28 -

6.2 Starting the program ..... - 28 -

6.3 Selecting a patient ..... - 29 -
6.3.1 Known patient ..... - 29 -
6.3.2 Adding a new patient ..... - 29 -
6.3.3 Editing patient data ..... - 29 -

6.4 Programming recorder ..... - 30 -

6.5 Attaching the cuff ..... - 32 -

6.6 Attaching the belt ..... - 32 -

6.7 Test measurement ..... - 32 -

6.8 Instructing the patient ..... - 33 -

6.9 Important measurement information ..... - 34 -

7. DOWNLOAD ..... - 34 -

7.1 Connecting the recorder ..... - 34 -

7.2 Start program ..... - 35 -

8. ANALYSE ..... - 35 -

8.1 Start program ..... - 35 -

8.2 Find/delete measurement results ..... - 36 -

8.3 Representations ..... - 37 -
8.3.1 Single values ..... - 37 -
8.3.2 Magnifying glass ..... - 38 -
8.3.3 Overview / statistics ..... - 39 -
8.3.4 Hourly mean values ..... - 40 -
8.3.5 Comparison ..... - 40 -
8.3.6 Histogram ..... - 41 -
8.3.7 Pie graphic ..... - 41 -

8.4 Additional buttons ..... - 41 -
8.4.1 Findings report ..... - 41 -
8.4.2 Print ..... - 42 -
8.4.3 PDF-Export ..... - 42 -
8.4.4 GDT -Export to general practice IT system ..... - 43 -
8.4.5 CSV-Export ..... - 43 -

9. ERROR CODES 44

10. CLEANING AND MAINTENANCE 45

10.1 Cleaning and disinfection of device surface 45

10.2 Cleaning and disinfection of cuffs 45

10.3 Functional check, Maintenance, STC and MTC 46
10.3.1 Functional check, Maintenance 46
10.3.2 Safety- and Measurement- technical check 46

10.4 Calibration mode 46

10.5 Disposing of the device 46

11. TECHNICAL INFORMATION 47

12. CHARGER 48

13. DELIVERY OVERVIEW 49

13.1 Standard delivery 49

13.2 Optional accessories 49

EU Declaration of Conformity

PAR Medizintechnik GmbH & Co. KG, Sachsendamm 6, 10829 Berlin

We declare that the medical device

PHYSIO-PORT, Hardware-Version **HW D**, Firmware-Version **FW 2.0**
(Including system-components and accessories)

is in conformity with the Medical Device Directive **93/42/EEC**
Including amendment **2007/47/EC**.

The medical device is defined as class IIa devices in accordance to annex IX of the Medical Device Directive. It is marked with

CE-0482

The medical device is designed, produced and verified under control of a quality system in accordance to EN ISO 13485:2012 + AC:2012 and annex II of the Medical Device Directive. The conformity of the quality system is certificated by:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2
20355 Hamburg
Germany

Berlin, August 17, 2015

PAR Medizintechnik GmbH & Co. KG

Engel

Dipl.-Ing. L. Engel
Technical Manager

1. General Information

1.1 To this manual

The greatest care has been taken in preparing this manual. However, if you still come across any incorrect details in this manual when using the system, then please contact us. This will allow us to correct any errors as soon as possible. The information and images contained in this manual are subject to any changes that may result from optical or technological developments
All trademarks stated and used in the text are the property of the present owner and are protected by law. All reproduction, translation and duplication in any shape or form – including extracts – require the written approval of the manufacturer. This manual is subject to updates by PAR Medizintechnik GmbH & Co. KG.

1.2 Confirmity

The product PHYSIO-PORT bears the CE marking **CE-0482** (notified body MEDCERT GmbH) indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices (including amendment 2007/47/EC) and fulfills the essential requirements of Annex I of this directive. It has an internal power source and is an MDD class IIa device.

1.3 Identifier

The device has an application part of the type 'BF'.

The product fulfills the requirements of the standard EN/IEC 60601-1 "Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance" as well as the electromagnetic immunity requirements of the standard EN/IEC 60601-1-2 " Medical electrical equipment – Collateral standard: Electromagnetic compatibility – Requirements and tests" and applicable amendments.

This symbol means:

Please consult the manual. It refers to things to which you should pay careful attention when using the device. This manual is an integral part of the equipment. It should be available to the equipment operator at all times. Close observance of the information given in the manual is a prerequisite for proper equipment performance and correct operation and ensures patient and operator safety. **Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.**

This manual reflects the equipment specifications and applicable safety standards valid at the time of printing.
All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
The quality assurance system used by PAR Medizintechnik GmbH & Co. KG in all the company facilities complies with standards EN ISO 9001 and EN ISO 13485.

The safety instructions in this manual are indicated in the following way:

CAUTION
This refers to a potentially dangerous situation failure to observe this warning may result in injuries and/or damage to the product.

In order to ensure the highest level of safety for patients and a minimum of interference, as well as keeping in line with the relevant testing precision level, the device should only be used in combination with original accessories provided by PAR Medizintechnik GmbH & Co. KG.

No warranty claims can be made in the event of any damage as a result of using other inappropriate accessories and consumable materials.

PAR Medizintechnik GmbH & Co. KG will only assume responsibility for devices in relation to their safety, reliability and functioning in the following cases:

- Assembly, enhancements, resettings, alterations and repairs carried out by PAR Medizintechnik GmbH & Co. KG, or at locations that have been expressly authorized by PAR Medizintechnik GmbH & Co. KG to carry out such repairs;
- Devices that have been used in accordance with their manuals.

2. Intended use:

PHYSIO-PORT are handy, patient-carried (long-term) blood pressure monitors for the measurement of non-invasive blood pressure. The devices work with the innovative technology of the upward blood pressure measurement ('IMT'), which considerably reduces the duration of the individual measurement compared to conventional blood pressure measuring devices. This greatly improves patient comfort. The switchover to the conventional mode, which operates by means of blood pressure measurement during the gradual release of the cuff pressure (down-measuring), is possible without problems during programming. PHYSIO-PORT can be used with adults, children and small children with their respective cuffs. The devices can carry out blood pressure measurements at different intervals for up to 48 hours (max. 400 individual measurements) and store the measurement results.

.

Notes on foreseeable misuse

*PHYSIO-PORT must **not** be used for newborn babies and is **not** suitable for use in Intensive Care Units.*
During a long-term blood pressure measurement, the instructions for the safety and functional reliability of the device must be observed.
The sensors should remain attached to the body over the entire period, according to the instructions of the medical personnel performing them.
No fluid should enter the device. If any fluid has entered the device, then it should only be used again after having been checked and approved by the Service Department.

2.1 Oscillometric Measurement Method

The blood pressure is measured by the oscillometric method. The criteria for this method are the pressure pulsations superimposed with every systole on the air pressure in the cuff. In order to measure the blood pressure, a blood pressure cuff wrapped around the upper arm needs to be inflated and subsequently deflated. The blood pressure is determined either during deflation of the cuff (deflation measurement method) or, by using a novel and faster technology, already during inflation of the cuff (inflation measurement method). The deflation measurement method is the most common method used. With this technique, the cuff is inflated to a pressure which must be clearly above the expected systolic value. Including cuff inflation, the measurement typically takes approx. 40 seconds (Figure A).

The inflation measurement method is a novel method based on the "**Inflation Measurement Technology (IMT)**" developed by PAR Medizintechnik. With this innovative technique, the cuff is inflated to a pressure just above the expected systolic value. Once the systolic value is determined, the cuff can immediately and quickly be deflated (Figure B).
The measurement typically takes only approx. 20 seconds. If disturbances occur during measurements with the inflation measurement method, which may be due to motion artifacts, for example, PHYSIO-PORT will automatically switch to the deflation measurement method and complete the blood pressure measurement.

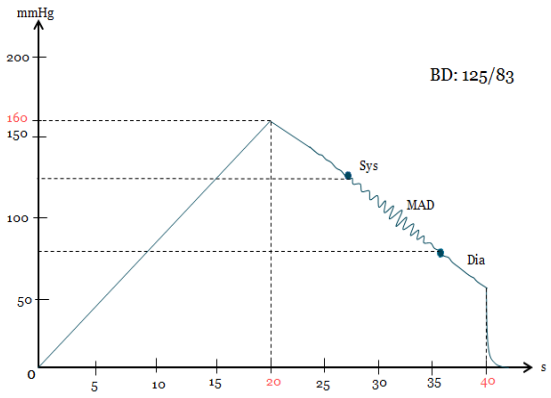


Figure A: Waveform representing the pressure in the cuff during a measurement using the deflation measurement method.

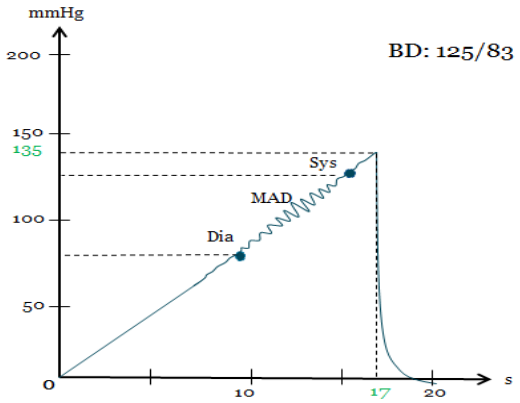


Figure B: ***Waveform representing the pressure in the cuff during a measurement using the inflation measurement method.***

With both methods, a pressure transducer measures the cuff pressure as well as the superimposed pressure pulsations. During blood pressure measurements, the cuff must be at heart level. If this is not ensured, the hydrostatic pressure of the liquid column in the blood vessels will lead to incorrect results. When the patient is sitting or standing during measurements, the cuff is automatically at the correct level.

2.2 Biocompatibility

The product components described in this manual, including accessories, which – when used for their intended purpose – come into contact with patients, have been explained in such a way that they conform to the biocompatibility requirements of the relevant standard when used for their intended purpose. If you have any questions in this regard, then please contact PAR Medizintechnik GmbH & Co. KG or one of its representatives.

2.3 Standards

- 93/42/EC
- 89/336/EEC
- EN 1060-1
- EN 1060-3
- DIN EN 60601-1
- DIN EN 80601-2-30

3. Safety Instruction an Use

Danger
• Risk of explosion •

The equipment is not designed for use in areas where an explosion hazard may occur. Explosion hazards may result from the use of flammable anesthetic mixtures with air or with oxygen, nitrous oxide (N2O), skin cleansing agents, or disinfectants.

CAUTION
• Rist to persons, Equipment damage •

Equipment may be connected to other equipment or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of equipment. Compliance with the standard IEC 60601-1 must always be ensured.

PHYSIO-PORT may be connected to a PC with the Physioportwin program. While connected to any of these devices, PHYSIO-PORT must be disconnected from the patient.

Before using the equipment, the operator must ascertain that it is in correct working order and operating condition.

CAUTION
• Rist to persons, Equipment damage •

The operator must be trained in the use of the equipment.

Only persons who are trained in the use of medical technical equipment and are capable of applying it properly are authorized to apply such equipment.

There are no user-replaceable components inside the equipment. Do not open the housing. For service or repair, please contact your local, authorized dealer.

4. PHYSIO-PORT Recorder

4.1 Operations controls

1 Cuff connection

2 Start/Stop button to trigger addittional measurements and to interrupt a measurement in process.

3 Day/Night button to change the measurement interval between day and night interval.

4 Info button to display the most recently values. The following values will be dislayed respectively:
- sytolic value „S/mmHg“
- diastolic value „D/mmHg“
- Puls frequency „HR/min-1“

5 LCD to display all information

6 On/Off switch

7 Battery compartment

8 Connection port to PC

9 Label with serial number

Figure 1

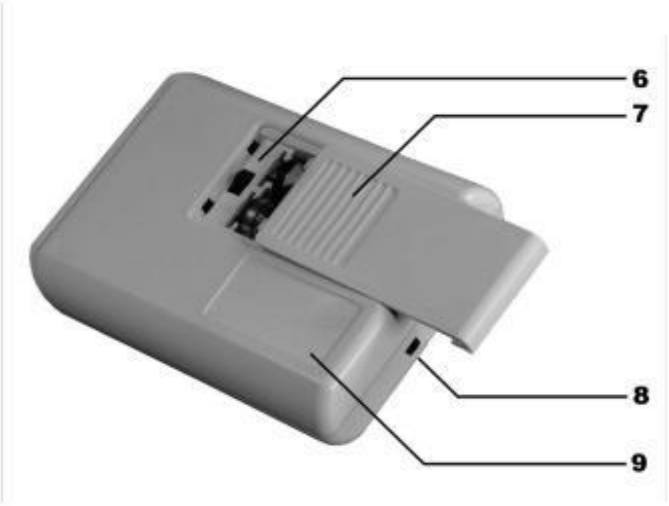


Figure 2

4.2 Button functions

During an ongoing long-term blood pressure measurement, the recorder keys have the following function:

To start and stop a measurement

To call the last measured values or the last error message

For manual switching of the Measurement intervals between day and night phase

Note

The manual switching between day and night phase is only possible, only if two measuring intervals are programmed and the day / night key is not deactivated.

If more or less measuring intervals have been set, then the day/night key has no influence on the measuring distances.

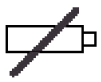
4.3 LCD display

The PHYSIO-PORT recorder has an LCD display with the measured values and all important information displayed.

4.3.1 *Displayed symbols*

M

- Flashes for ever detected oscillation
- Displayed constantly when measurement data hes been stored



- Flashes when batteries are running out

Continuous display when batteries are empty and no measurements can be made

- Day phase has been selected

- Night phase has been selceted

4.3.2 *Time display*

The built-in clock of the recorder is automatically set at the current PC time. A manual change of recorder time is not possible.

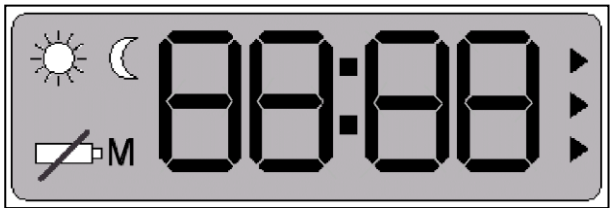


Figure 3: LC-Display of the PHYSIO-PORT

4.3.3 *Functional control*

The PHYSIO-PORT recorder will automatically carry out a self-test when it is switched on, which will activate all symbols and segments of the LCD display.
The device will then check the inserted (rechargeable) batteries and will display the available capacity. In this context, e.g. 'C100' refers to a 100% (rechargeable) battery capacity (fully charged) and 'C50' refers to a 50% (rechargeable) battery capacity (half empty).

In order to carry out a 24 hour measurement, the capacity needs to be at least 90%.
If the capacity is below 90%, then you will need to insert new batteries or fully-charged rechargeable batteries.

When the self-test has been completed successfully, the following information will appear on the display after the power supply test:

- The actual time
- The measurement phase (day/night)
- Whether any measurement data has been stored (display: M)

4.4 Power supply

4.4.1 *General*

The PHYSIO-PORT Recorder requires either two nickel metal hydride rechargeable batteries, or two alkaline batteries.

When starting the recorder via the Physioportwin software, please ensure that the relevant power source has been selected (see 6.6 Programming the recorder).

In addition, the device also has a built-in lithium cell to indicate the time. The capacity of two fully-charged rechargeable batteries or two new batteries ensures at least 48 hours of operation or 400 measurements.
Battery capacity reduces in line with increased use. If the capacity of the two fully-charged rechargeable batteries clearly falls below 24 operating hours, then you need to replace them.

Always insert two fully-charged rechargeable batteries or two new batteries, before taking a new measurement.

Note
Charge the rechargeable NiMH batteries to capacity before using them for the first time.

4.4.2 *Inserting batteries*

The battery compartment is located on the underside of the recorder. In order to open this compartment, use your thumb to move the battery compartment lid approx. 6 mm backwards and then remove the lid in an upward direction.

Figure 4: Opening of the battery compartment

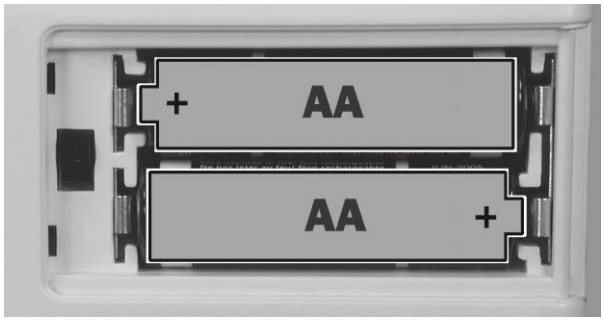


Figure 5: Observe polarity

Note
Make sure that the installed batteries have correctly polarity !!

4.5 PHYSIO-PORT Cuffs

Various cuff sizes are available for the PHYSIO-PORT (standard, large and children size).
Please select the correct cuff size (see printed text on the cuff) .
Replace the cuffs at regular intervals.

CAUTION
• Incorrect measurement •

Cuffs that are too small will result in measurements that are too high. Cuffs that are too large will result in measurements that are too low.
Damaged Velcro fasteners may lead to incorrect measurements.

4.6 Connections

4.6.1 *Connection of the cuff to the recorder*

To connect the blood pressure cuff to the recorder, plug the metal connection of the cuff as far as possible into the connection point at the recorder, until it clearly clicks into place.
The cuff can be removed again from the recorder by pulling back the external metal plug cover.

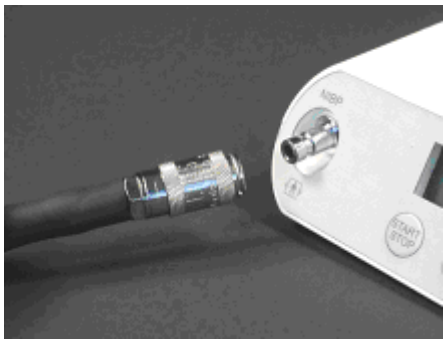


Figure 6: Cuff connection of PHYSIO-PORT

4.6.2 *The connection cable to the recorder*

In order to start the recorder and read information from it, the recorder must be connected to the PC via a USB connecting cable.

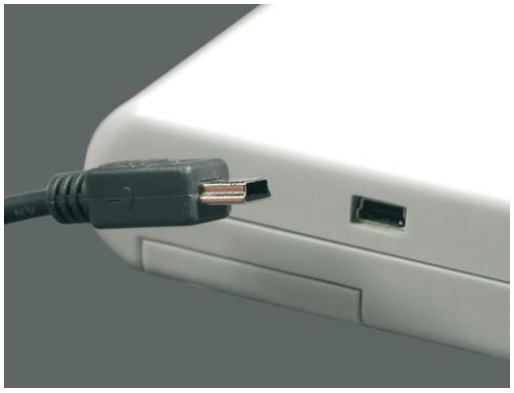


Figure 7: Connection of the Mini-USB cable

5. Software Installation

5.1 PC software Physioportwin

Insert the Physioportwin CD in the CD ROM drive.
If the CD drive does not automatically start up, start "setup.exe" (on the Physioport CD) via Windows Explorer.

CAUTION
The program must be installed with Administrator rights.

The selection menu for the installation language appears on the PC display. Later the program language can be changed via “Settings”.

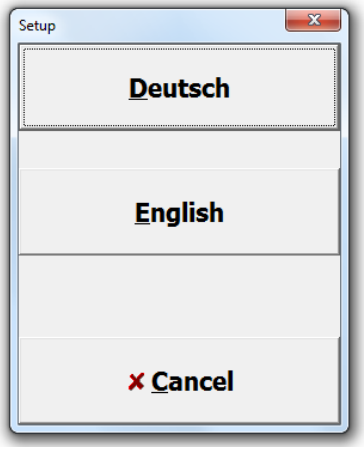


Figure 8: Selection menu of the installation language

After selection of the language starts the software installation.

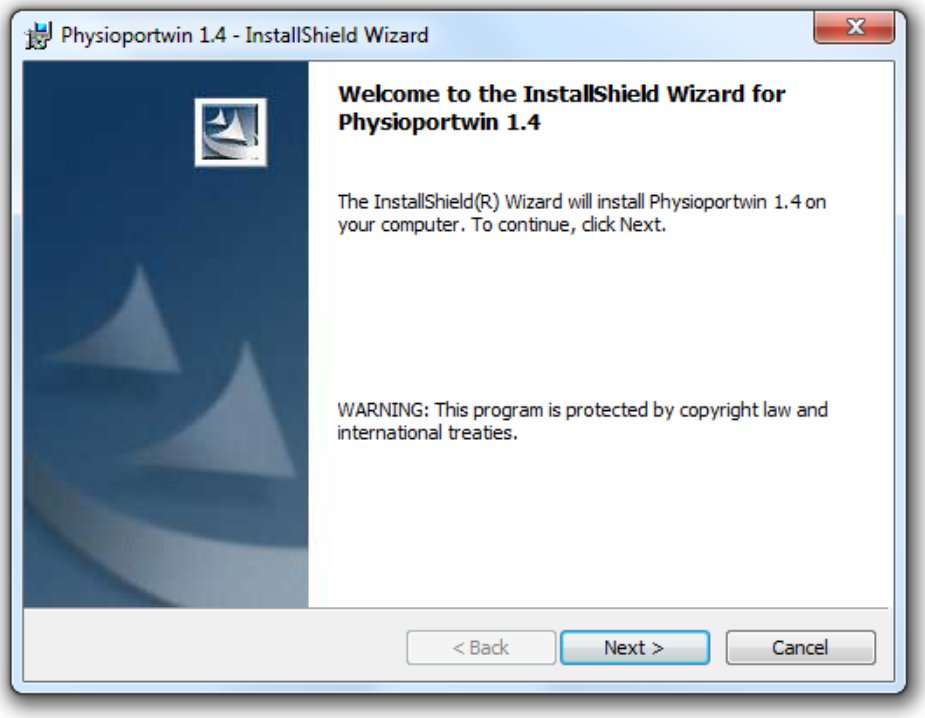


Figure 9: Software Installation

Selection of the destination. folder. Click Change to install to a different folder or click Next to install to this default folder.

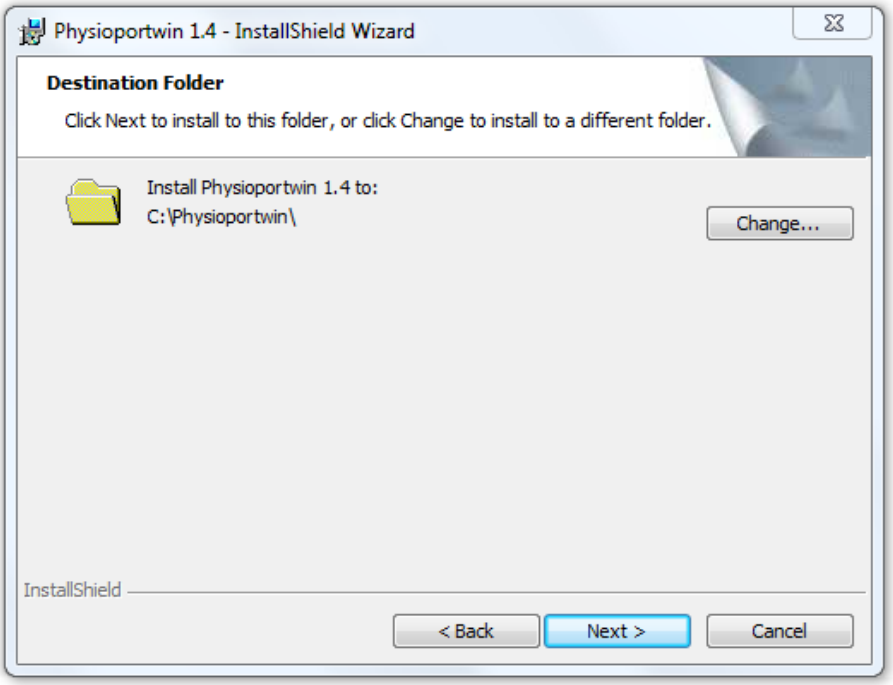


Figure 10: Destination Folder

Displaying of the installation settings. Click Install to begin of the software installation.

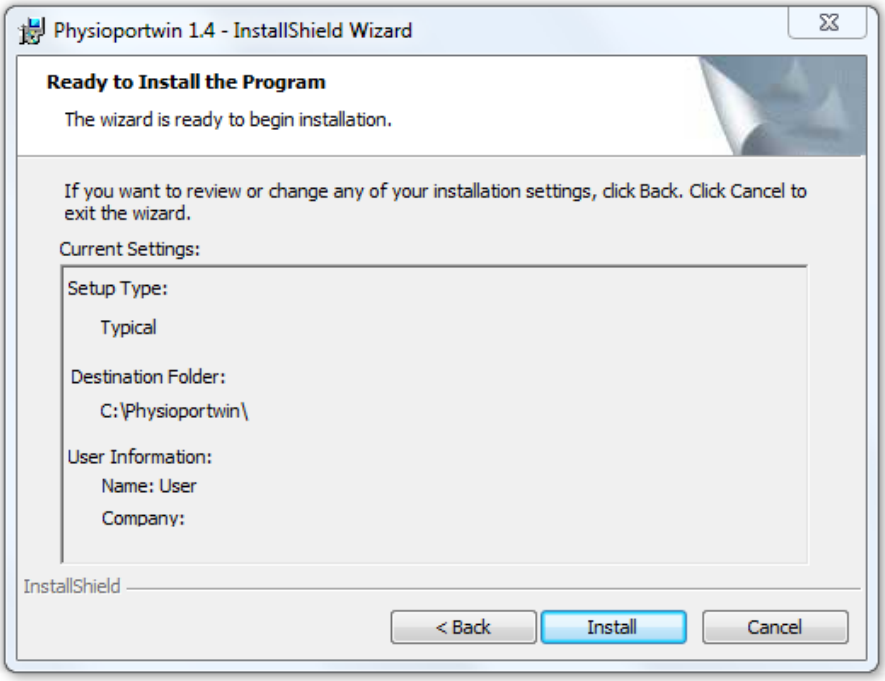


Figure 11: Display of the installation settings

Click Finish to complete the software installation..

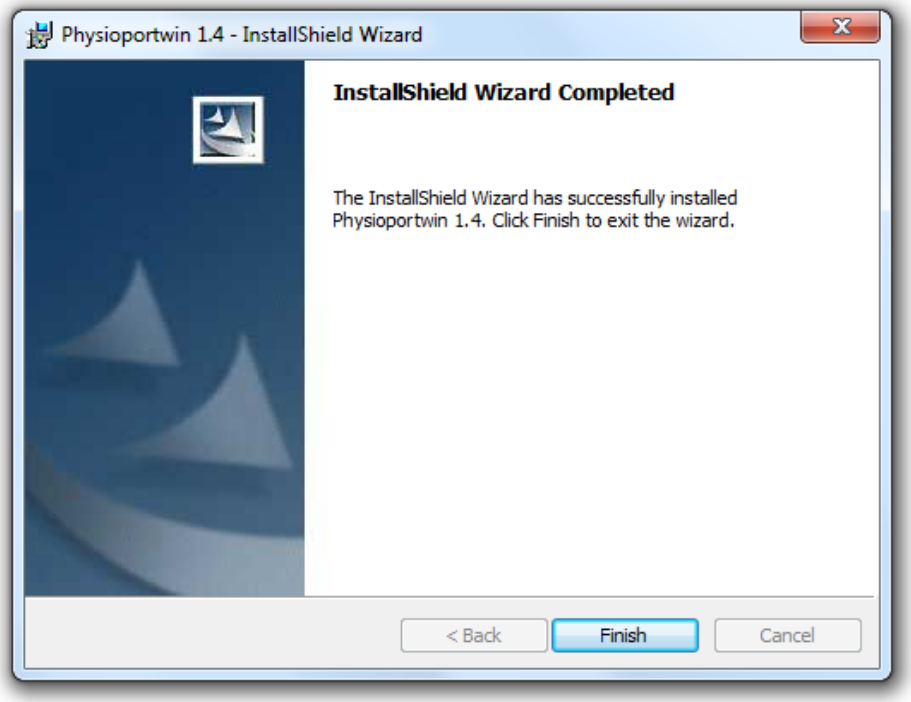


Figure 12: End of the software installation

5.2 Settings

Click **Settings** to get the configuration of the program.

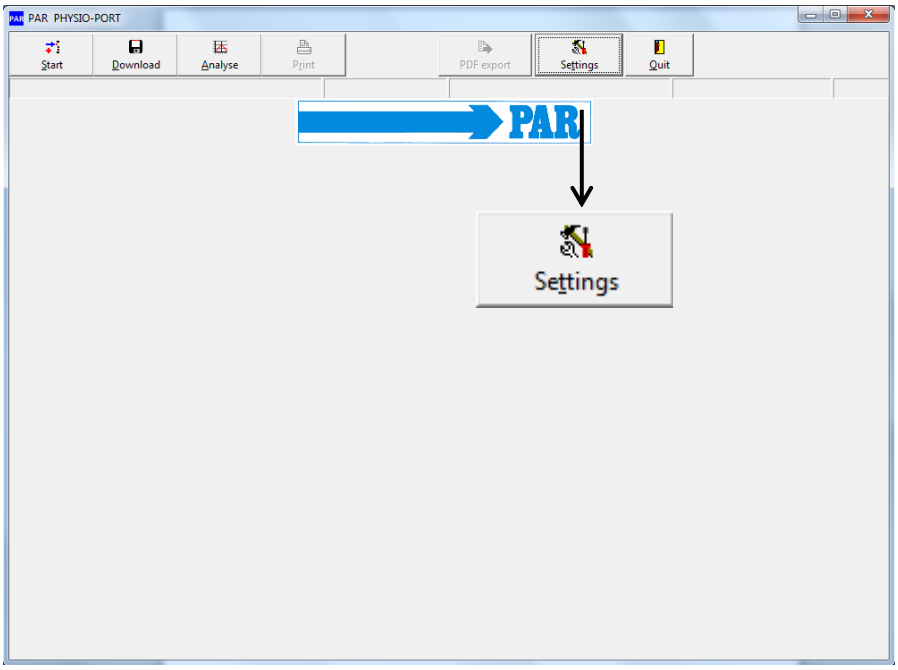


Figure 13: Settings

The different settings are split on four tabs.

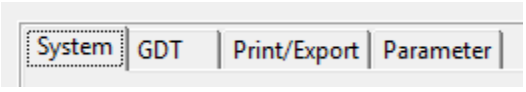


Figure 14: Tabs for program settings

5.2.1 *System*

All default settings of PHYSIO-PORT-System are made on this tabsheet.

It´s recommended to locate the connected recorder automatically.

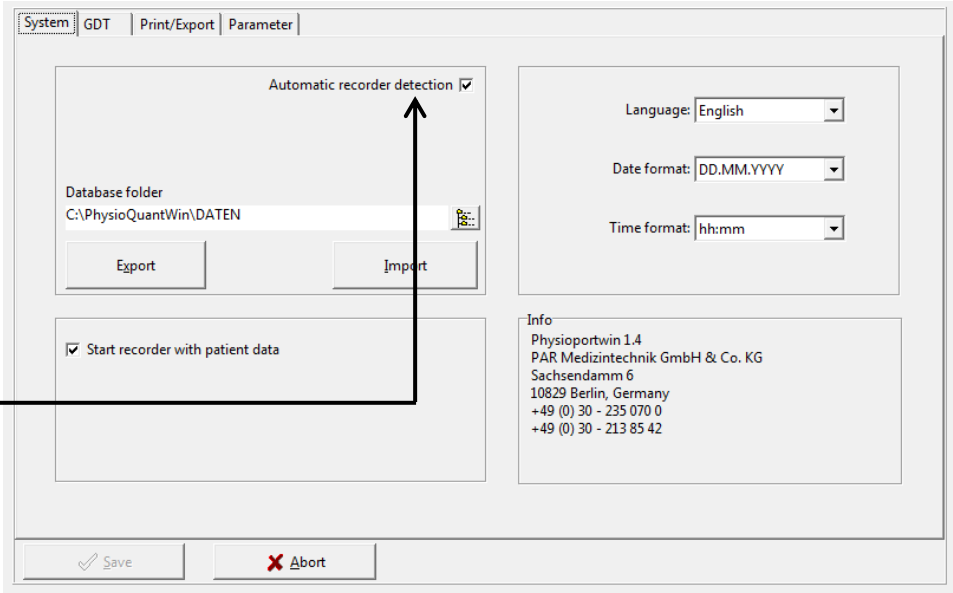


Figure 15: Setting page for system settings

It´s possible to select the interface manually, too.

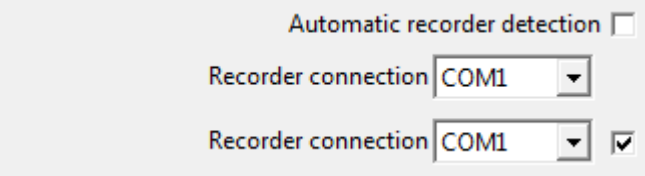


Figure 16: Recorder connection

This setting allows to start the recorder with or without patient data.

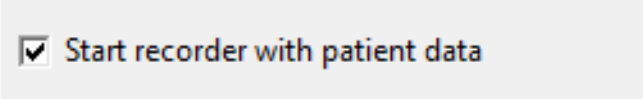


Figure 17: Enter of patient data

The database folder for PHYSIO-PORT can be set to another folder (see network installation).

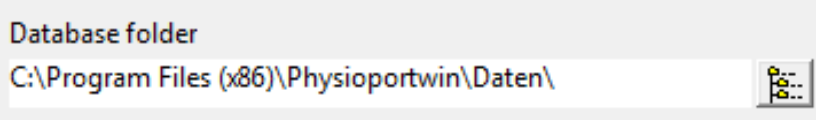


Figure 18: Database folder

The function [EXPORT] backups the database into the backup folder. It´s recommended to save the actual database before importing the database! The function [IMPORT] restores the saved database.

Figure 19: Sicherung der Datenbank

CAUTION
• Lost of data •
The restoration [IMPORT] of the database overwrites the actual database!
It´s recommended to save the actual database **before** importing the database.

The program language, date format and time format can be selected manually.

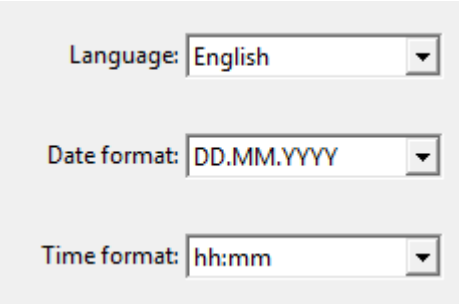


Figure 20: Language, Date format and Time format

5.2.2 *GDT interface*

The GDT interface is a standard produced by the German Quality Assurance Medical Software (QMS – 'Qualitätsring Medizinische Software') for system-independent data transfer between medical devices and general practice IT systems.
The Physioportwin software has an integrated GDT interface ('Device Data Carrier interface' – '**G**eräte-**D**aten-**T**räger') and therefore allows for easy data transfer with a general practice IT system

On this tabsheet all settings can be set to connect with IT systems via GDT interface.

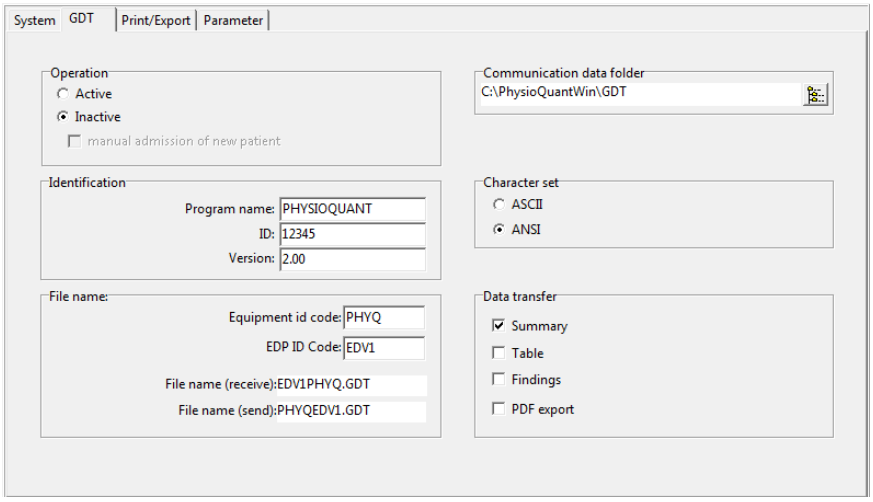


Figure 21: GDT settings

Please contact your general practice IT dealer to find out what the correct settings of the GDT interface are in relation to the relevant IT system. All standard settings in the GDT standard (Version 2.0) can be adjusted on an individual basis.

Operation:
This setting activates and deactivates the GDT interface.

When the GDT interface is activated, the software will check during the start of the program whether the defined GDT data is available and processes it. If no data is found, then a 'normal' program start will take place.

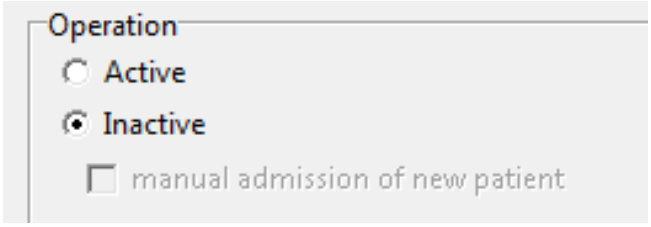


Figure 22: Activation of GDT interface

Note

During GDT operation, the option for manually adding new patients should not be active, so as to avoid any incorrect input or non-corresponding patient master data (general practice IT system and PHYSIO-PORT database).

Identification:
The ID is a unique identifier that consists of a minimum of 1 and a maximum of 8 characters, which uniquely identifies the PHYSIO-PORT system during GDT data transfer.

File name:
The file names that are used for the communication between general practice IT systems and PHYSIO-PORT software should be entered in the '**File name**' field. File names consists of a **device identification code** (1 - 4 characters), e.g. PHYQ, and a **EDV identification code** (1 - 4 characters) for the general practice IT systems, e.g. EDV1.
Both these identification codes are then used to create file names, which will always have the extension *.GDT.

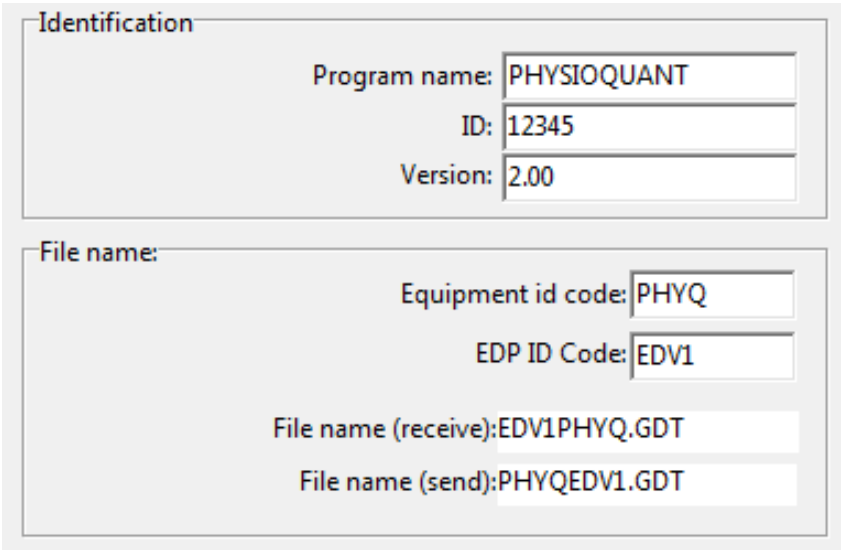


Figure 23: GDT identification and filename

Folder for communication data files:
The data transfer folder can be created where you want. In order to avoid any networks errors, a separate folder should be created for each individual work station (e.g. on a local PC).
CAUTION: GDT data files will need to be read and then deleted by the general practice IT system, before any further GDT data files can be generated.

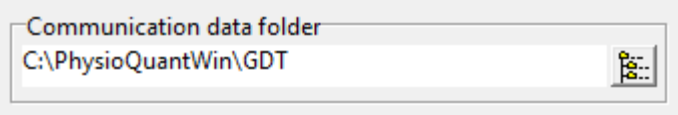


Figure 24: Folder for communication data files

Character set:
Actual used character set can be selected (ASCII or ANSI). It concerns the representation of äöüß during the data transfer.

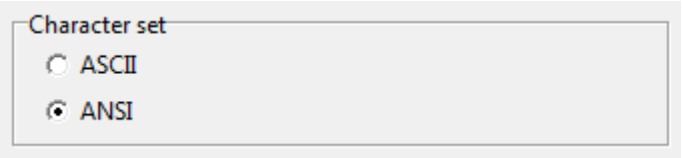


Figure 25: Character set

Data transfer*:*
Prior selection will determine which data is transferred to general practice IT system.

Figure 26: Setting of data transfer

5.2.3 *Print/Export*

The default setting for printing and exporting of analysis are made on this tabsheet.

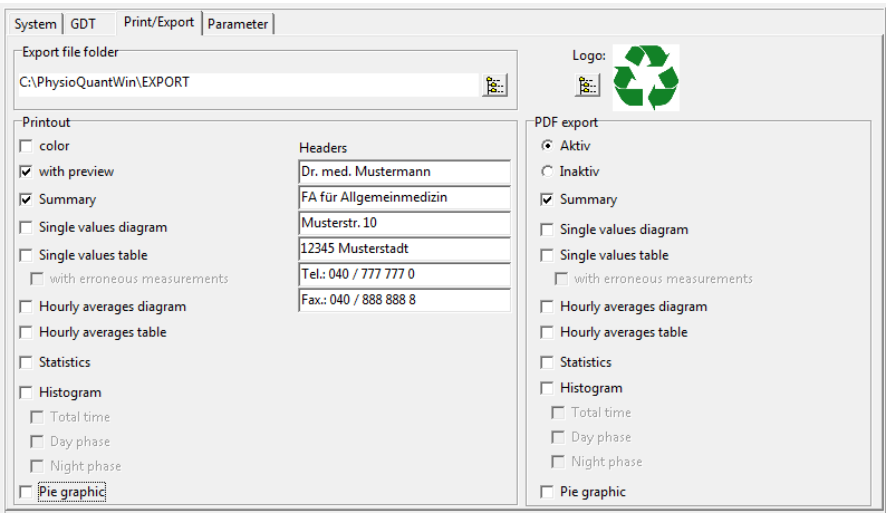


Figure 27: Setting page for print and export of analysis

Print out:
Set of the default printout pages, preview and colored print out.

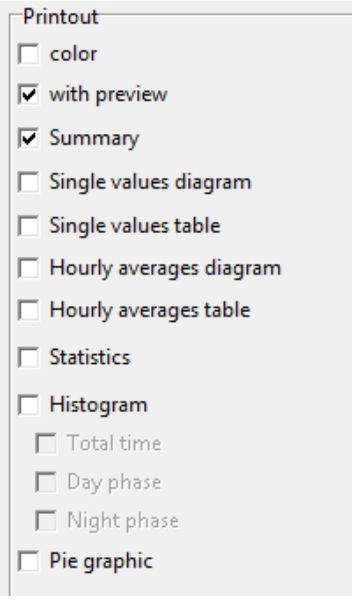


Figure 28: Configuration of print out

Entered headers are printed on every print out.

Figure 29: Headers for print out

Selected logo is printed on every print out.

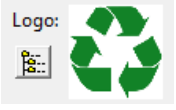


Figure 30: Logo

Export:

Physioportwin can stores print outs as PDF file (file extension **.PDF**) und the measurements as CSV file (file extension **.TXT**). The file name contains all relevant information.

P^<type>_<workstation>^<slot#>_<id>^<last>^<first>_<StartTime>_<exportTime> **. PDF / .TXT**

^	= Delimiter within the block
<type>	= "REPORT" for print
<workstation>	= name of workstation
<slot#>	= 1 (slot number on the workstation)
<id>	= Patient number
<last>	= Last name
<first>	= First name
<StartTime>	= Start time of the measurement (format: YYYYMMDDHHMMSS)
<exportTime>	= Creation time of the PDF file (format: YYYYMMDDHHMMSS)

For example: P^REPORT_Comp^1_12345^Maier^Hans-Peter_20031216104632_20040318153145.pdf

Activation of the PDF export and selection of default exported pages.

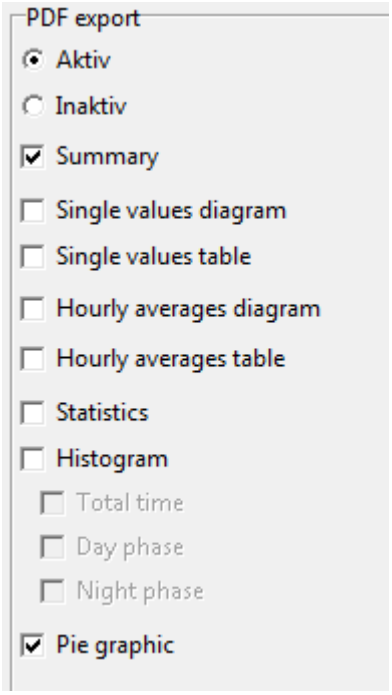


Figure 31: Configuration of PDF Export

Selection of folder for export files.

Figure 32: Folder for export file

5.2.4 *Parameter*

The default setting for analysis of long time measurements are made on this tab sheet.

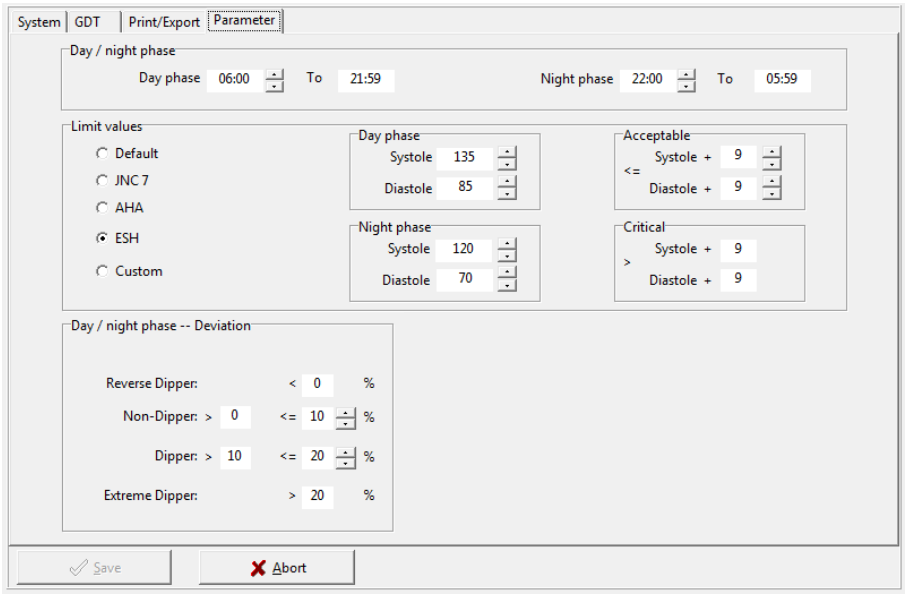


Figure 33: Configuration of parameter

Day and night phase:
Default values can be set.

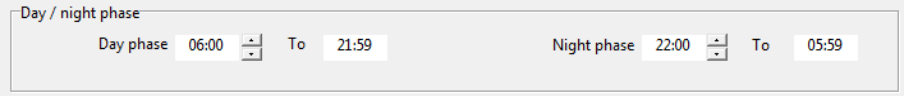


Figure 34: Default values for day and night phase

Limit values:
Limit values for day and night phase can be set. These limit values are represented as lines in the graphical representation of the evaluation and are entered into the statistical calculations.

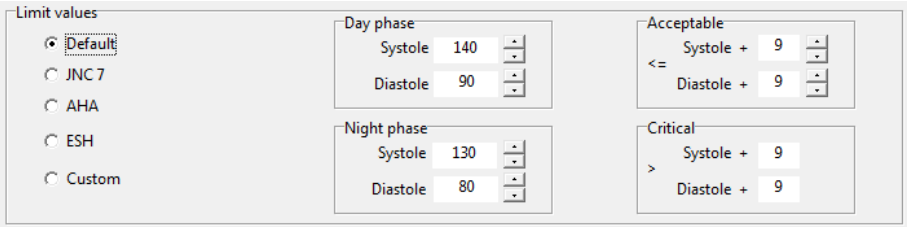


Figure 35: Limit values

Limits for the nightly pressure drop can be defined.

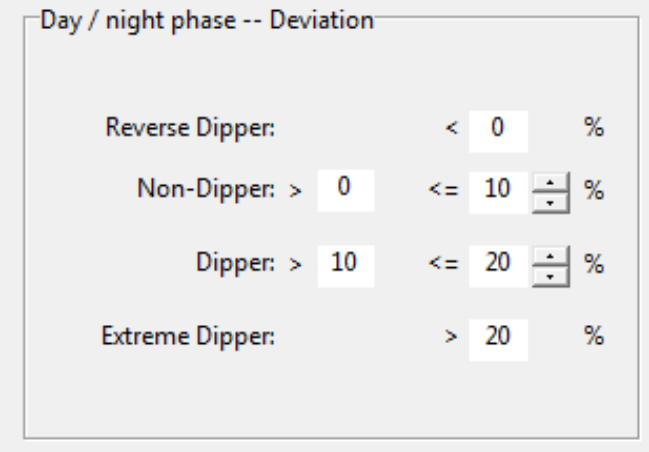


Figure 36: Setting of dipper limit values

5.3 Network Installation

The Physioportwin software can be used in networks. This allows for central storage of patient information and measurements (i.e. on the server). This information can then be accessed from all workstations.

To this end, a corresponding directory is first created on the central server. This folder must be connected as a 'drive' on all workstations.

A local program installation is then carried out on all workstations that will use the PHYSIO-PORT PC Software (as described in Section 5 Installation).

The folder for the shared database is then created under [Settings], whereby selection is facilitated by the integrated Explorer functionality.

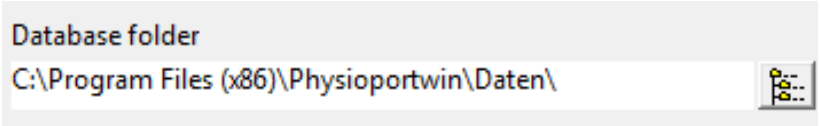


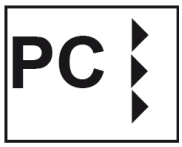
Figure 37: Database folder

6. Commencing Long Term Blood Pressure Measurement

6.1 Connecting the recorder

Connect the PHYSIO-PORT Recorder to the PC and switch on the recorder. The on/off switch is located beneath the lid of the battery compartment.

The recorder display will show after self-test:



6.2 Starting the program

After the PHYSIO-PORT software has started, the main screen appears. To program the recorder, click on the [**Start**] button to open the relevant menu.

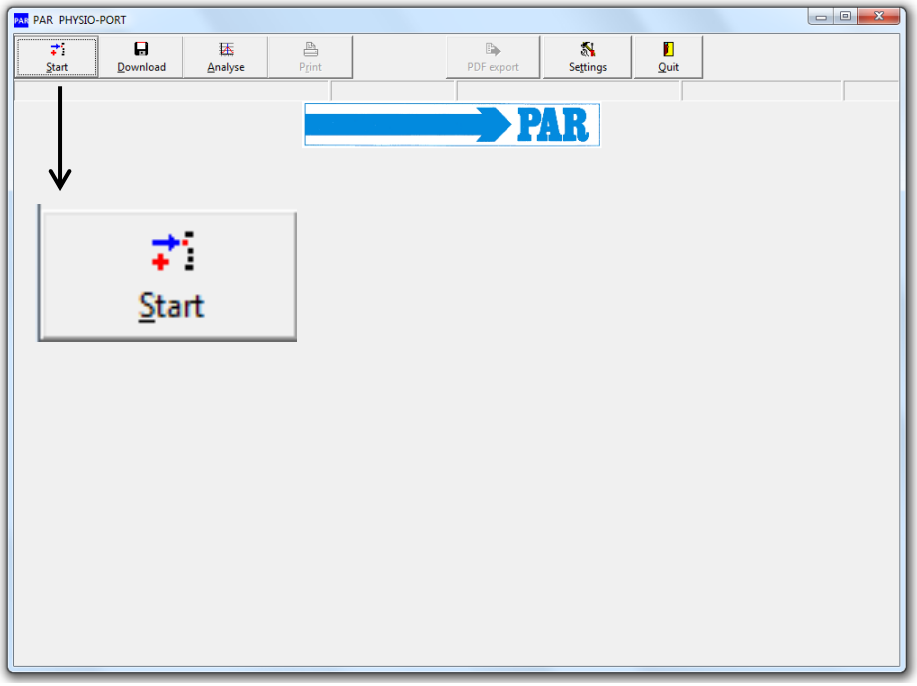


Figure 38: Main menu: Start

6.3 Selecting a patient

6.3.1 *Known patient*

The selection window of the patient database appears:

In the 'NAME' field, enter the first letter of the patient's surname. All patients whose names start with this letter will then be displayed (e.g. those beginning with **M**): Select the required patient, by double clicking on the relevant line.

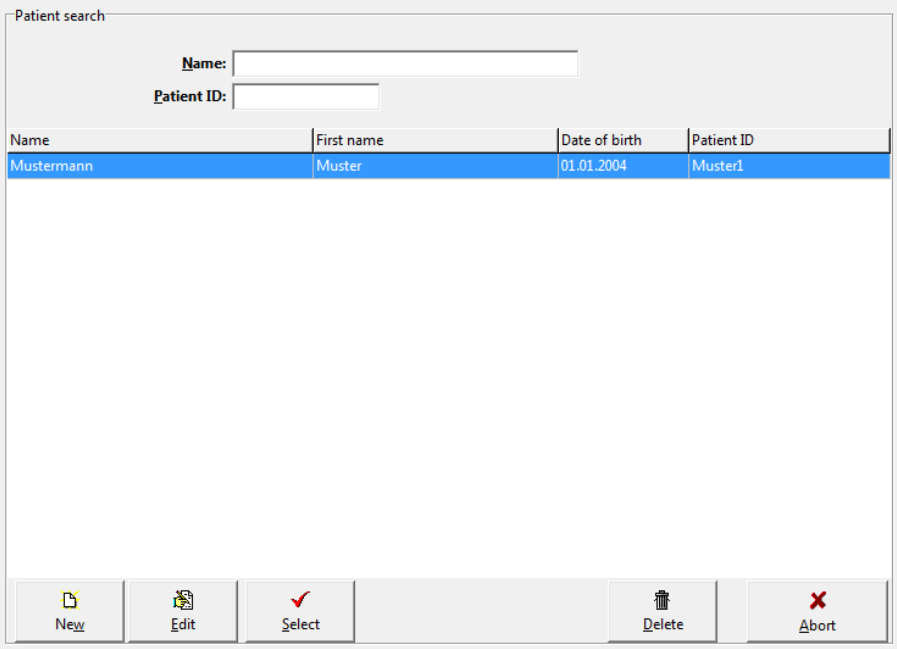


Figure 39: Selecting a patient

6.3.2 *Adding a new patient*

If the required patient is not in the database, then you can directly enter new patient data.

To do so, open the entry screen with the **[New]** button. Enter all the required data and save it to the database with **[Save]**:

Figure 40: Adding of a new patient

6.3.3 *Editing patient data*

Patient data that has been entered can be edited and updated at any time (**[Edit]** button in the Patient selection window).

EXCEPTION: Patient ID cannot be changed once it has been entered and saved!

6.4 Programming recorder

After you have selected the patient, a window will appear for configuring and programming the PHYSIO-PORT Recorder.

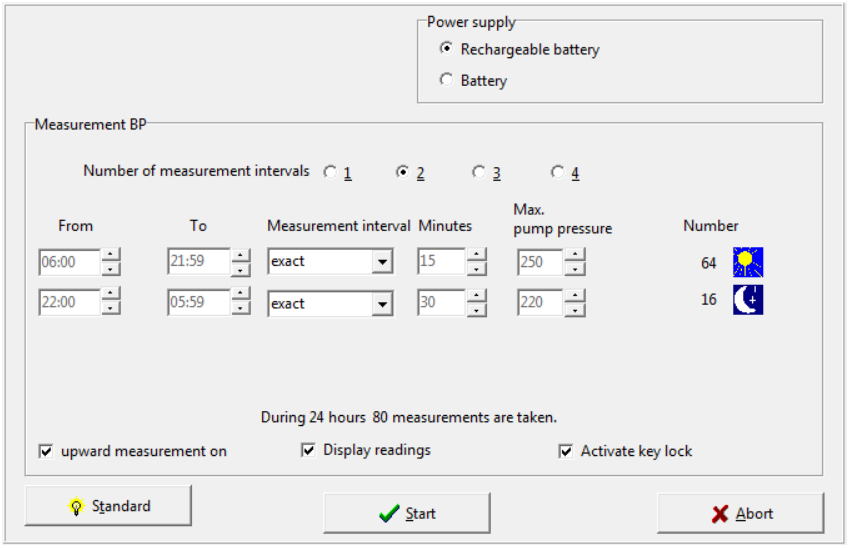


Figure 41: Configuration of the measurement

Number of measurement intervals: Up to 4 different measurement intervals can be selected. The standard setting is at 2 intervals (day and night phase) .

Power supply: The type (normal battery or rechargeable battery) that is used for long term measurements is set.

From.. To..: The beginning and end of selected intervals can be set in minutes.

Measurement interval: Exact: measurements are taken at the exact intervals in minutes that have been set.
Approx.: measurements randomly vary at approx. +/- 2 minutes around the times set

Minutes: The interval between subsequent measurements can be programmed to range between 2 and 120 minutes.

Max. pump pressure: Limits the max. cuff pressure to the value set between 200 mmHg and 280 mmHg.

Number: The number of all programmed measurements will be displayed for each measurement interval and a summary is provided for each 24 hours.

Display readings: The blood pressure values are displayed on the LCD of the recorder.

Activate key lock: Day and night phase can be switched.

Upward measurement on:

The inflation measurement method is activated (**Inflation Measurement Technology, IMT)**

Standard:

The **[Standard]** button will reset the parameters to the following values:

2 measurement Interval

Interval 1 (day phase):	Intervall 2 (night phase):
06:00 - 21:59	22:00 - 05:59
exact every 15 min	exact every 30 min

After saving the selected configuration, the starting sequence of the recorder will commence by clicking on the **[Start]** button. The recorder will first check whether there are any previous measurements that have not yet been read. If this is the case, then a warning will be displayed.
If this is not the case, then the recorder will be switched off and the new patient data and measurement intervals are stored in the recorder.

CAUTION

• Patient interchange •

The recorder must be restarted on each new measurement by Physioportwin software. Otherwise, new measurements are assigned to the old patient.

Only when a new long-term measurement is started, will the recorder delete all old patient data and measurement values.

6.5 Attaching the cuff

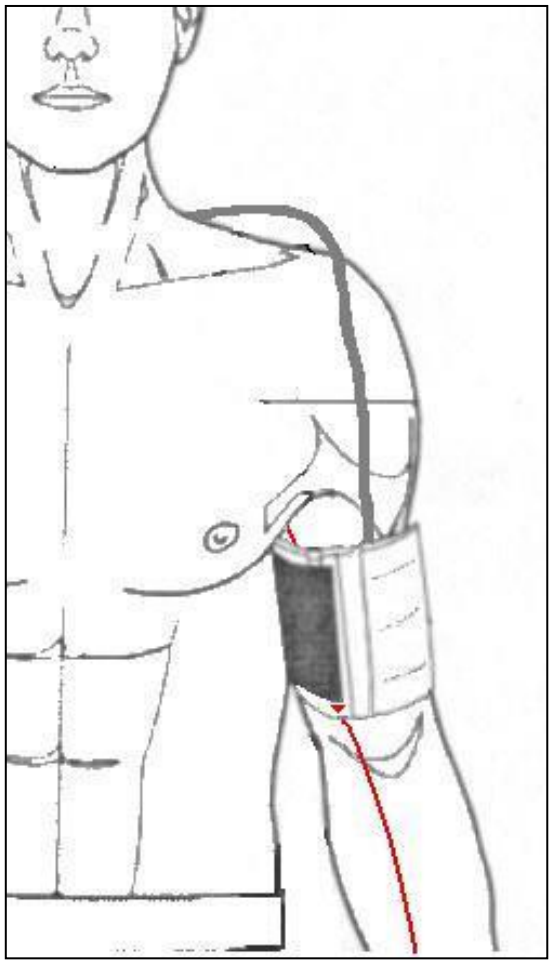


Figure 42: Attaching the cuff

CAUTION
• Risk tot he patient •
The PHYSIO-PORT Recorder must not be connected to a PC, while it is being attached to the patient.

Please remove the connecting cable to the PC.

Attach the cuff to the arm that is less used by the patients. For adults: approx. 2 finger widths above the elbow. For children: slightly closer to the elbow. Ensure that the cuff does not rise up when the arm is being bent.

Please ensure that:

- the connecting tube points upwards to the shoulder
- the side of the cuff with 'Patient' written on it makes contact with the skin
- the arrow lies over both the arteria brachialis and arteria femoralis
- the cuff is attached tightly and closely surrounds the tissue, but exerts no pressure on the veins

Switch on the PHYSIO-PORT Recorder and place it in the carrier bag.

6.6 Attaching the belt

Use the belt to attach the bag to the body of the patient. For hygienic reasons, the bag should not come into direct contact with the skin.

Place the cuff tube around the patient's neck in order to release any strain and connect it to the PHYSIO-PORT.
Ensure that the tube cannot become disconnected while the measurement is being taken.

6.7 Test measurement

A test measurement must always be carried out after the cuff has been attached and the recorder connected.
In order to avoid any incorrect measurements, please ensure that the patient remains calm while the measurement is being taken. The patient may stand up or sit down.
Begin the measurement by pressing the Start/Stop button.

After a brief moment, the device will inflate the cuff. Blood pressure measurement is performed during inflation, if the IMT method selected. Otherwise once the required inflation pressure has been

reached, the device will gradually decrease the pressure. Cuff pressures are displayed and for every detected oscillation the letter '**M**' will be displayed. Once the measurement has been taken, the following information is displayed sequentially:

- Systolic value (S/mmHg)
- Diastolic value (D/mmHg)
- Pulse rate (HR/min-1)

If an error message is displayed instead of the measurement value, e.g. 'E 08' (insufficient recognition of oscillation), then attach the cuff more firmly and press the Start/Stop button again.

If the test measurement has been successful, then the device is ready for automatic measurement.

6.8 Instructing the patient

Explain to the patient how the device works (automatic blood pressure measurement at regular intervals) and make the following points:

- Stay calm during the measurement, so that there will be no incorrect readings as a result of any movement by the patient;
- During the night, it is best to place the PHYSIO-PORT Recorder in its carrier bag on the bedside table;
- It is possible to manually switch between the day phase and the night phase;
- Record any unusual events in the patient diary (master copy on CD) and also carry out an additional measurement with the Start/Stop button if this happens;
- At any time, measurement can be interrupted via the Start/Stop button. Cuff pressure will then decrease;
- Do not open the battery compartment.

CAUTION
• Risk to the patient •
*Cancel the measurement with the **Start/Stop button**, if the cuff remains inflated for more than approx. 2 minutes.*
Take off the cuff if it remains inflated after pressing the Start/Stop button. It may be that the tube has been disconnected.
Further measurements should only be carried out after the cuff has been correctly attached again.

6.9 Important measurement information

It is recommended to operate the unit in the IMT mode. This considerably shortens the measurement time of a single measurement and thus offers a greatly increased comfort with significantly reduced stress on the patient.
If the IMT mode not selected then the device will inflate the cuff to approx. 160 mmHg (starting pressure). For subsequent measurements, the inflation pressure will be 25mmHg above the last measured systolic value (minimum 120mmHg).
If the measurement value is in excess of the inflation pressure, then additional inflation of 50 mmHg will take place.

A manual measurement can be taken at any time between automatic measurements. This will be indicated by '+' in the measurement value table.

After an incorrect measurement, the measurement will be repeated after 2 minutes. An error message is only displayed in the error table with its corresponding error code after 3 incorrect measurements.

After the error messages 'E04' (Empty battery/rechargeable battery), 'E07' (Inflation time finished) and 'E10' (400 measurements carried out), the measurement will not be repeated. After error message 'E07', the subsequent measurement will again take place according to the selected measurement cycle.

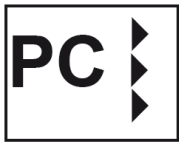
After error messages 'E04' and 'E10' have been displayed, the device will switch to a power-saving mode, in order to avoid complete discharge of the rechargeable batteries. This mode can only be cancelled by switching the device on and off.

7. Download

7.1 Connecting the recorder

Connect the PHYSIO-PORT Recorder to the PC and switch on the recorder. The on/off switch is located beneath the lid of the battery compartment.

The recorder display will show after self-test:



7.2 Start program

After the PHYSIO-PORT software has started, the main screen appears. To program the recorder, click on the [**Download**] button to open the relevant menu.

The measured values are read from the recorder and stored in the database for the corresponding patient.

The graphical evaluation of the results is then displayed.

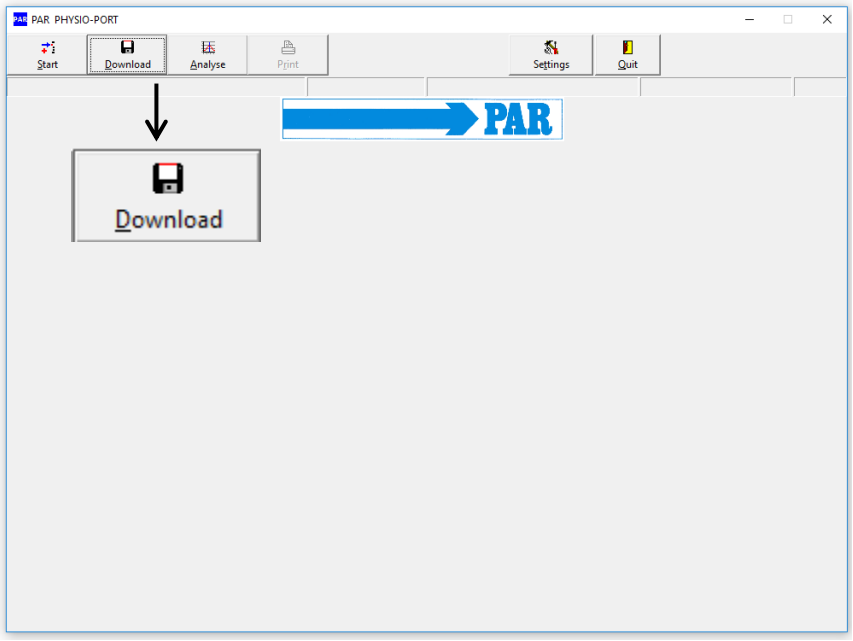


Figure 43: : Main menu: Download

8. Analyse

8.1 Start program

After the PHYSIO-PORT software has started, the main screen appears. To program the recorder, click on the [**Analyse**] button to open the relevant menu.

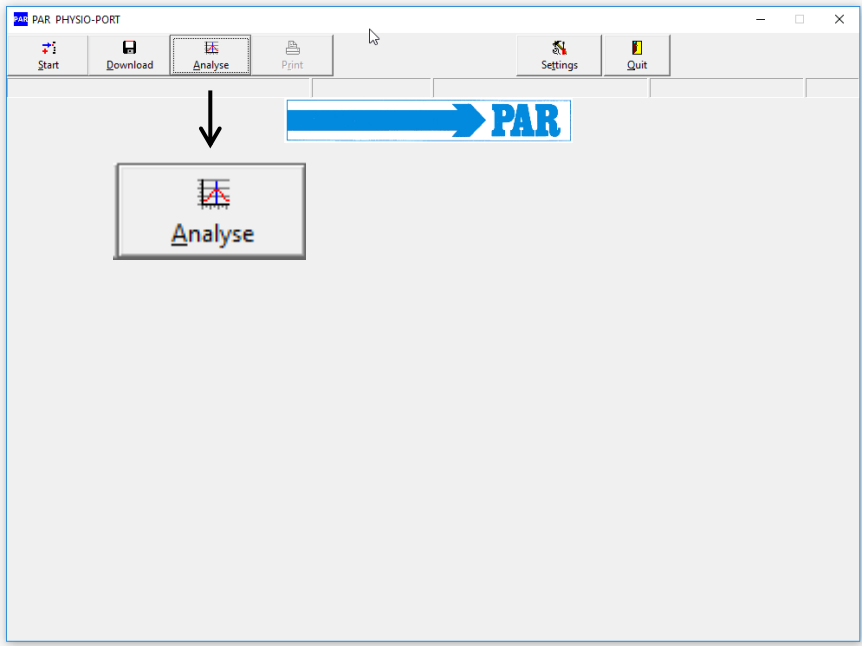


Figure 44: Main menu: Analyse

8.2 Find/delete measurement results

The selection window of the patient database is displayed. Select the required patient. The measurement result selection window appears for those patients whose data have been stored in the database. You can request the relevant saved measurement results by double clicking on the relevant data in the selection window.

In order to delete a specific measurement result from the database, you need to click on the relevant date line in the selection window (the line will appear in blue). Then click on **[Delete]**. After a confirmation message appears, the result will be deleted.

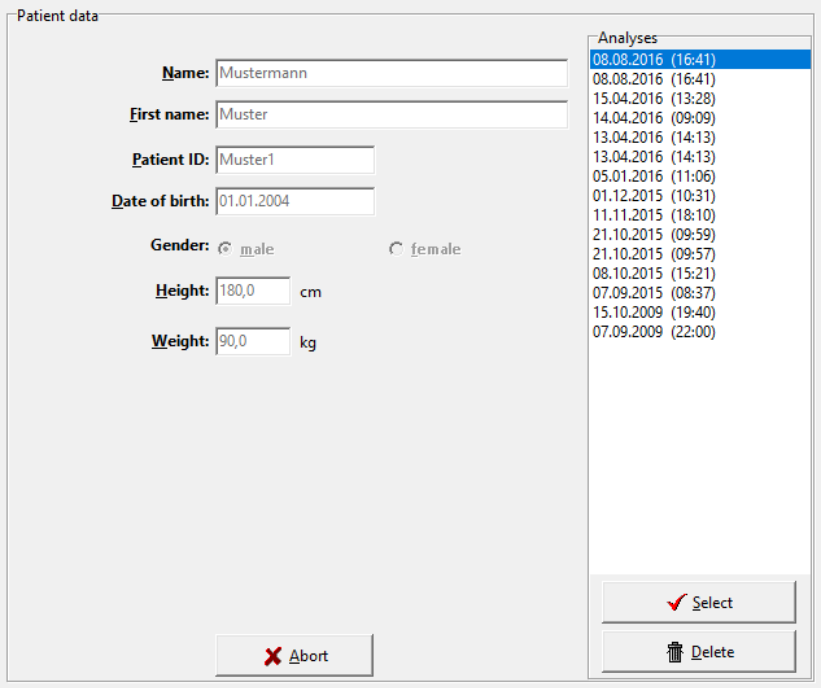


Figure 45: Selection of analysis

8.3 Representations

8.3.1 *Single values*

This graph displays the results of all individual measurements. The set critical values for the day and the night phase are displayed as red lines.

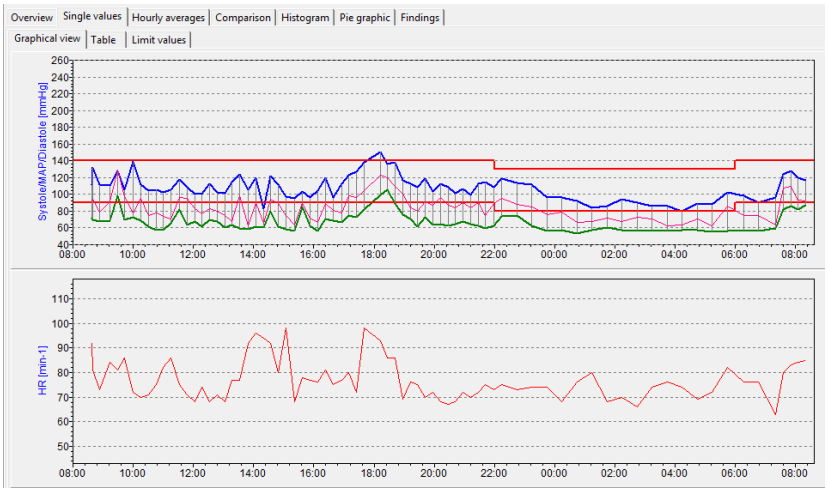


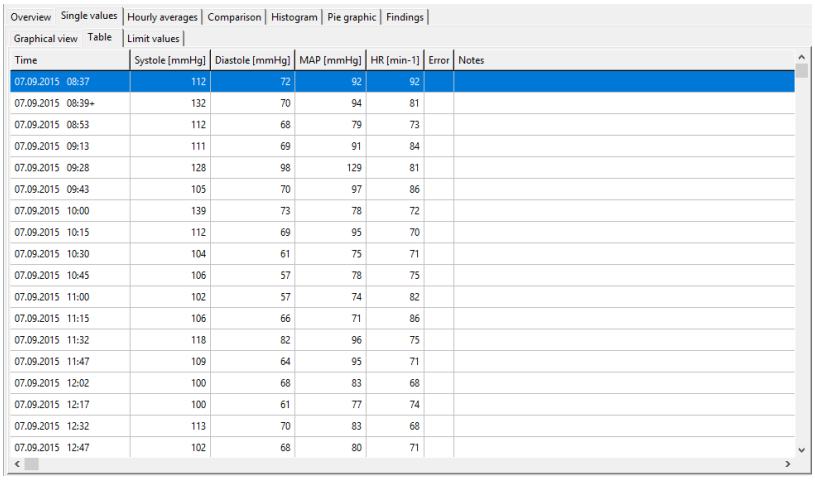
Figure 46: Graphical single values

All measurement results are listed by date/time, systole, diastole, heart rate and mean pressure.

Additional measurements (that have been carried out manually by using the Start/Stop button) are displayed behind the time indication and marked with the '+' symbol.

Meaning of the mark:
+: Manual measurement
*: Night phase
#: Day / Night phase was switched manually

In order to delete individual measurements, you need to click on the relevant line (the line will appear in blue). Then click on **[Delete]**. After a confirmation message appears, the measurement will be deleted.



Time	Systole [mmHg]	Diastole [mmHg]	MAP [mmHg]	HR [min-1]	Error	Notes
07.09.2015 08:37	112	72	92	92		
07.09.2015 08:39+	132	70	94	81		
07.09.2015 08:53	112	68	79	73		
07.09.2015 09:13	111	69	91	84		
07.09.2015 09:28	128	98	129	81		
07.09.2015 09:43	105	70	97	86		
07.09.2015 10:00	139	73	78	72		
07.09.2015 10:15	112	69	95	70		
07.09.2015 10:30	104	61	75	71		
07.09.2015 10:45	106	57	78	75		
07.09.2015 11:00	102	57	74	82		
07.09.2015 11:15	106	66	71	86		
07.09.2015 11:32	118	82	96	75		
07.09.2015 11:47	109	64	95	71		
07.09.2015 12:02	100	68	83	68		
07.09.2015 12:17	100	61	77	74		
07.09.2015 12:32	113	70	83	68		
07.09.2015 12:47	102	68	80	71		

Figure 47: Tabular single values

The limit values, day / night phase, the tabular and graphic individual values are summarized. The limit values and the day / night phase can be set individually. The following settings are available for the limit values: Default setting, JNC 7, AHA, ESH and custom.

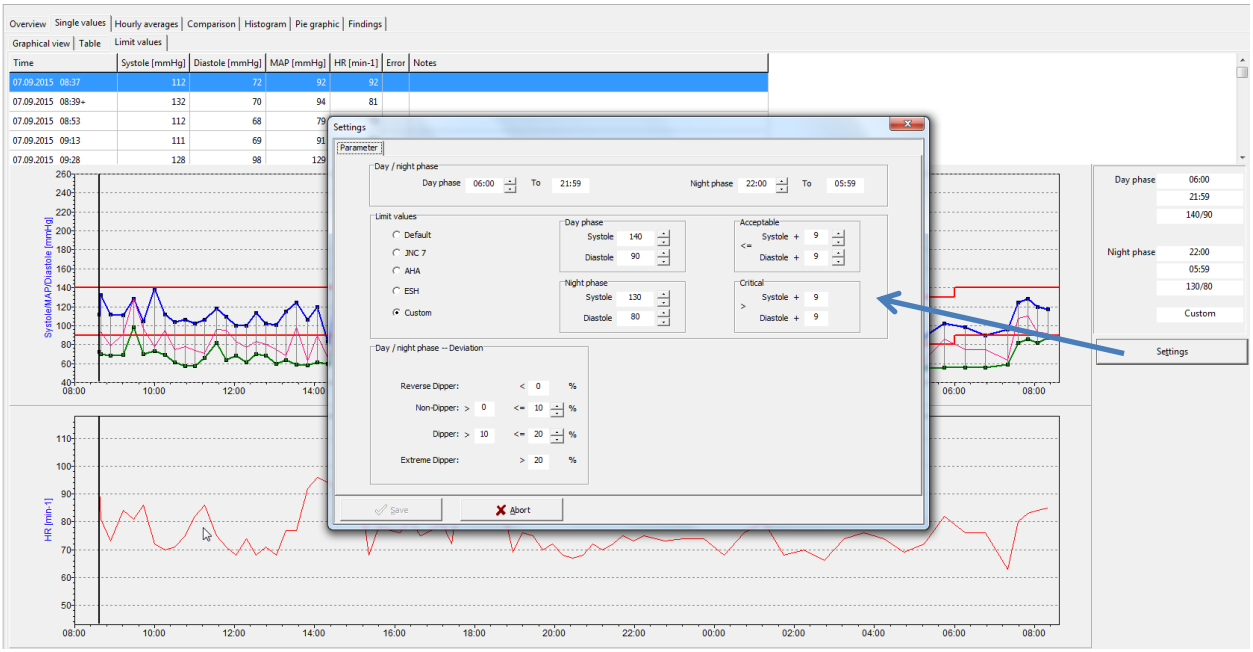


Figure 48: Limit values

8.3.2 *Magnifying glass*

The integrated magnifying function is used to display the measured values more precisely..
A mouse click in the graphics activates the magnifying glass, another click again shows the complete evaluation.

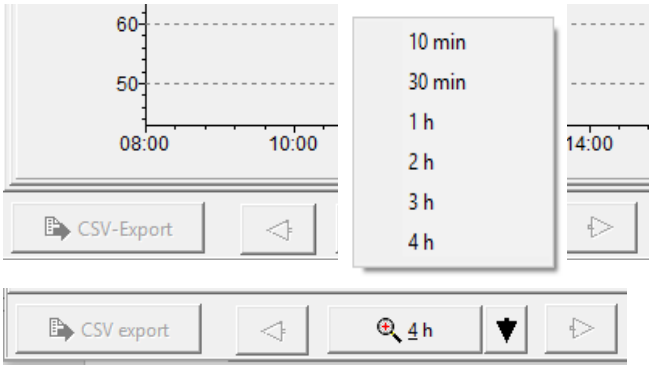


Figure 49: Magnifying glass

The saved measurement values can be represented in various ways, by clicking on the relevant tabs.

Figure 50: Select representation

8.3.3 *Overview / statistics*

The overview displays a numerical summary of the long-term blood pressure measurements, as well as the statistical measurement results, for the whole monitoring period, according to day and night phase.

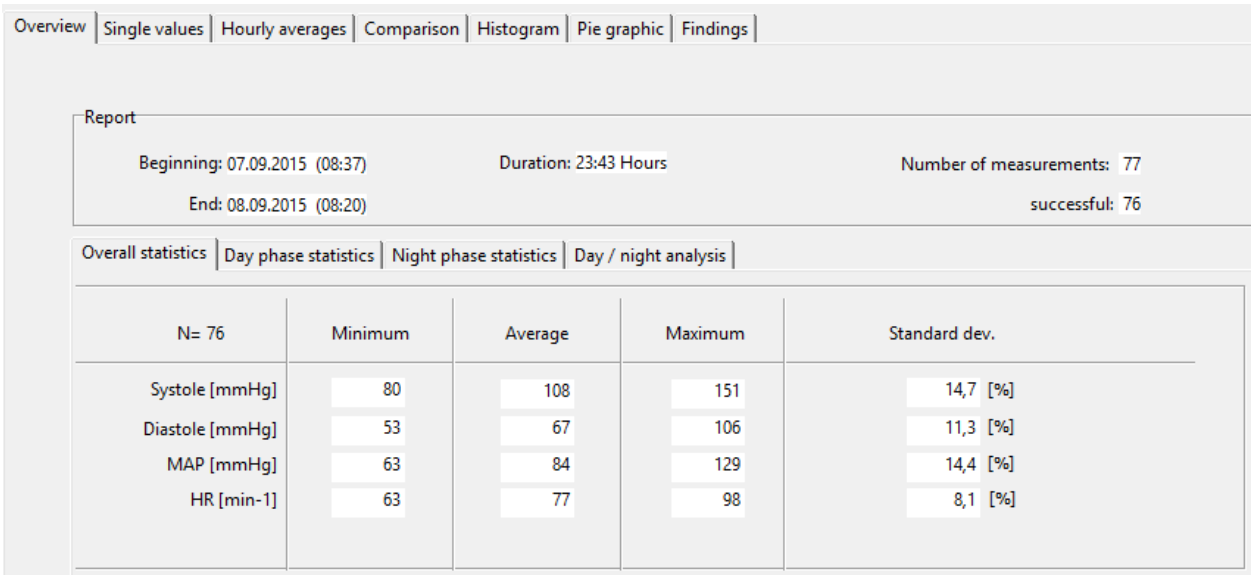


Figure 51: Overview statistics

The software calculates dipper, non-dipper, extreme dipper or reverse dipper values in the overview of the day / night analysis:

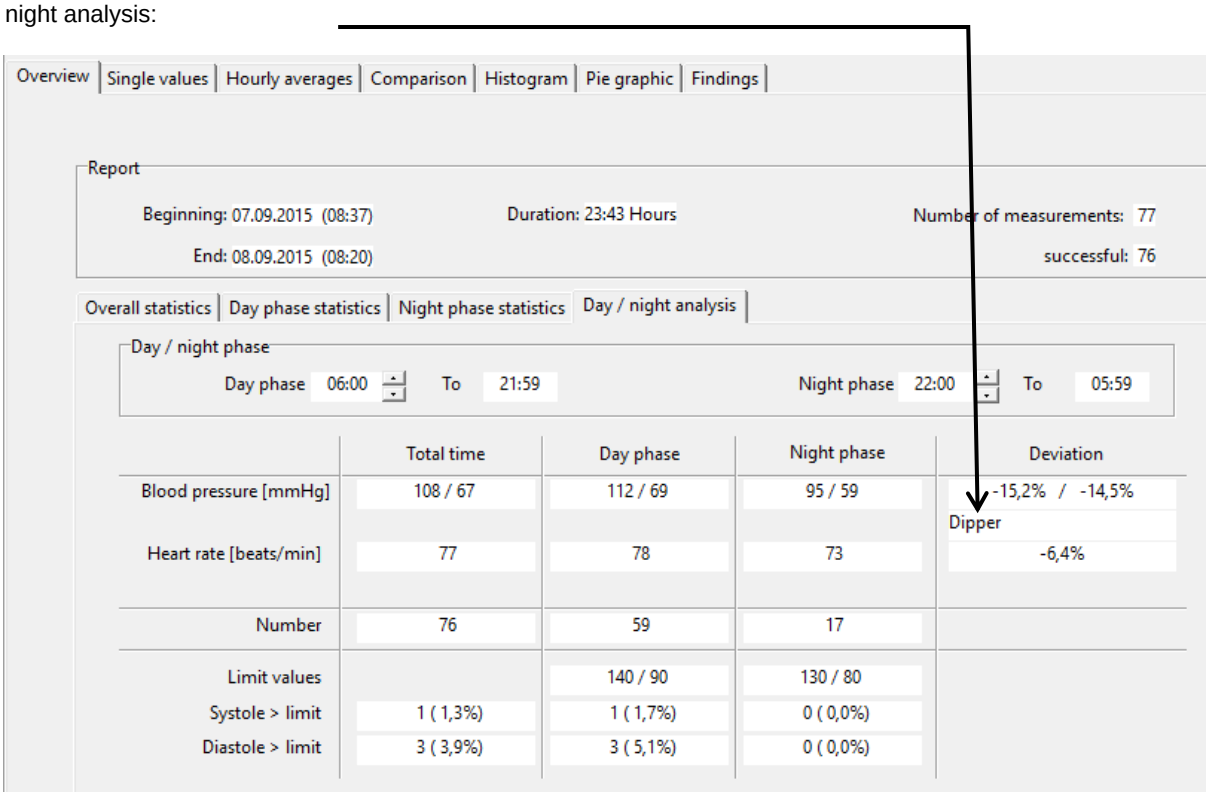


Figure 52: View of a day / night analysis with information about the dipper type of the patient

8.3.4 *Hourly mean values*

Overview | Single values | Hourly averages | Comparison | Histogram | Pie graphic | Findings

Graphical view | Table

Time	Systole [mmHg]	Diastole [mmHg]	MAP [mmHg]	HR [min-1]	PD [mmHg]	PRP / 1000	Number
07.09.2015 08:00 - 09:00	118,7	70,0	88,3	82,0	48,7	9,7	3
07.09.2015 09:00 - 10:00	114,7	79,0	105,7	83,7	35,7	9,6	3
07.09.2015 10:00 - 11:00	115,3	65,0	81,5	72,0	50,3	8,3	4
07.09.2015 11:00 - 12:00	108,8	67,3	84,0	78,5	41,5	8,5	4
07.09.2015 12:00 - 13:00	103,8	66,8	80,8	70,3	37,0	7,3	4
07.09.2015 13:00 - 14:00	111,5	60,3	76,0	78,5	51,3	8,8	4
07.09.2015 14:00 - 15:00	109,3	65,5	84,8	90,5	43,8	9,9	4
07.09.2015 15:00 - 16:00	97,8	65,3	75,3	80,3	32,5	7,8	4
07.09.2015 16:00 - 17:00	108,3	65,8	78,8	77,3	42,5	8,4	4
07.09.2015 17:00 - 18:00	129,3	76,7	99,3	83,3	52,7	10,8	3

Figure 53: Tabular hourly mean values

In order to ensure a clear representation, the calculated hourly mean values are only displayed as a graph and a table.

8.3.5 *Comparison*

A comparison or a contrasting of two measurement series in both graphical and tabular form is also possible.

Date	07.09.2015 (08:37)	15.10.2009 (19:40)
Blood pressure [mmHg]		
Total time	108 / 67	124 / 70
Day phase	112 / 69	137 / 81
Night phase	95 / 59	118 / 64
Deviation	-15,2% / -14,5%	-13,9% / -21,0%
	Dipper	Dipper
Heart rate [beats/min]		
Total time	77	68
Day phase	78	77
Night phase	73	68
Deviation	-6,4%	-11,7%

Figure 54: Comparion of two measurement series

8.3.6 *Histogram*

The histogram presentation of measured values is possible.

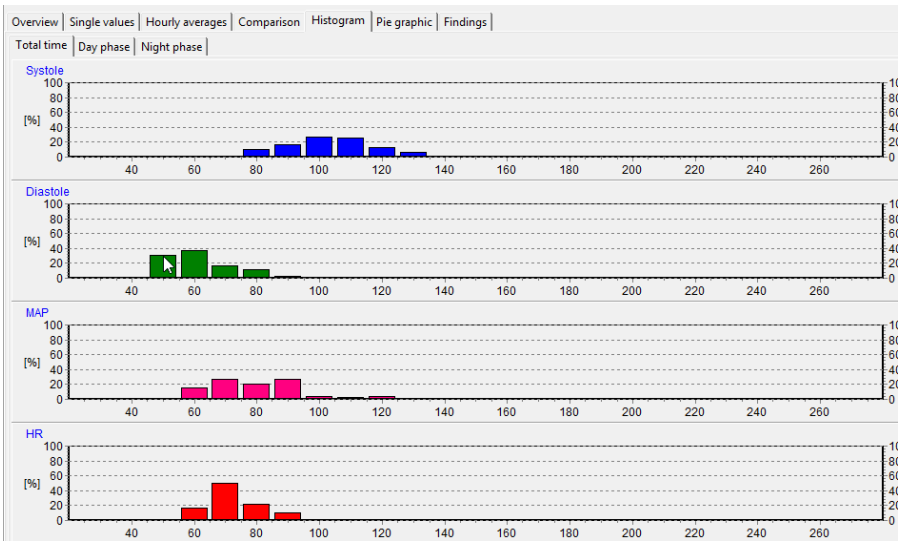


Figure 55: Histogram of the measurered values

8.3.7 *Pie graphic*

The measured values can also be displayed as a pie graphic.

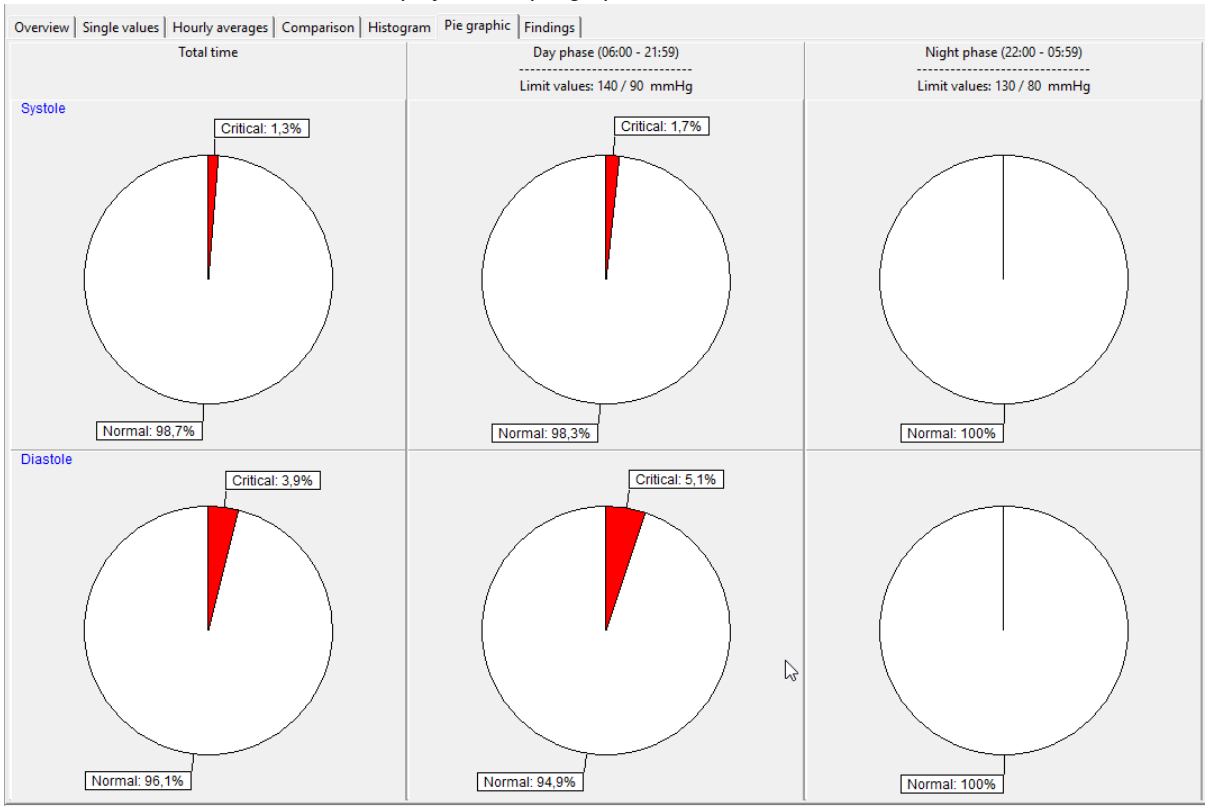


Figure 56: Presentation of the values a pie graphic

8.4 Additional buttons

8.4.1 *Findings report*

You can create a small report in relation to the findings of the long-term blood pressure measurements. This text will be summarised and can – when activated – also be forwarded to the general practice IT system.

8.4.2 *Print*

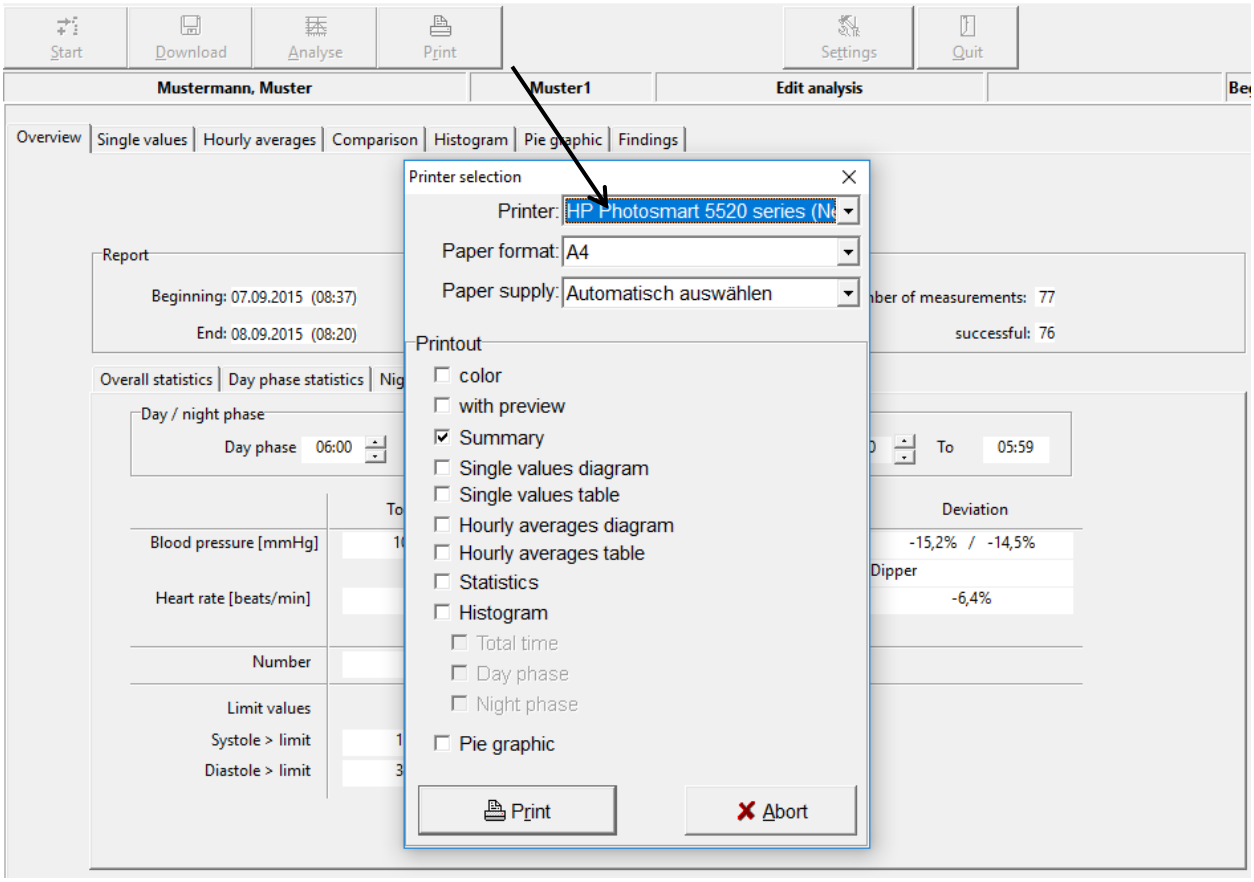


Figure 57: Selection of pages

You can print every page displaying measurement results by using the **[Print]** button.

The size of the printout can be determined on an individual basis. You can define a standard format under 'Settings'

8.4.3 *PDF-Export*

The [PDF Export] button creates PDF files from the print pages - the file name contains all patient information.
The size of the PDF export can be determined on an individual basis. You can define a standard format under 'Settings' .

8.4.4 *GDT -Export to general practice IT system*

If the PHYSIO-PORT software of the general practice IT system interface has been activated, you can then create a GDT file in accordance with the selected settings by using the **[GDT export]** tab, which will be saved in the configured directory.

8.4.5 *CSV-Export*

The [CSV Export] button creates a formatted text file with all measured values. This file is stored in the export directory. The file name contains all patient information.

9. Error codes

E 03 Internal hardware error (contact the Service Department).

E 04 Batteries are empty. This is displayed as soon as the batteries have insufficient capacity to carry out measurements.

E 05 Measurement time has elapsed. This is displayed when measurement time (without inflation time) exceeds 60 seconds.

E 06 This error code will be displayed when:

- the actual cuff pressure exceeds the maximum allowable inflation pressure of 280 mmHg;
- the device is not inflating beyond the set maximum pressure and is waiting for the next measurement time.

E 07 The maximum inflation time of 60 seconds has elapsed. Error refers to a loose cuff or tube, or another faulty sealing.

E 08 Insufficient oscillations have been detected:
At least 8 oscillations need to be detected for a correct measurement. The cuff should be attached sufficiently tightly (you should be able to put one finger beneath the cuff, but not two). PHYSIO-PORT will regulate the deflation rate for follow-up measurements accordingly.

E 10 Memory full. 200 blood pressure measurements have been carried out and the memory of the device is full.

E 11 Movement during diastole recognition.

E 12 Diastole is outside of the measurement range.

E 20 Systole is outside of the measurement range.

(E12 and E20 are displayed when the calculated systole or diastole values are outside the range in which the oscillations are recorded.)

E 21 Systole is below the measurement range.

E 22 Systole is above the measurement range.

E 24 Difference between systole and diastole is too small (10 mmHg or less)

E 23 Movement during systole recognition.

Air deflation speed is too high, e.g. as a result of leakage.

10. Cleaning and Maintenance

10.1 Cleaning and disinfection of device surface

Switch off the PHYSIO-PORT Recorder.
Use only a moist cloth and ensure that no fluid enters the device. The most commonly used cleaning and disinfection agents in practices and clinics can be used.

10.2 Cleaning and disinfection of cuffs

Light stains can be removed by using a moist cloth.

For heavier stains, rinse the cuff with soapsuds or disinfected cleaning agent (not in the washing machine!). No fluid should enter the cuff inflation section or the connecting tube (therefore please remove the inflation section when cleaning the cuff).

After you have cleaned the cuff, you need to rinse it thoroughly with water and let it dry at room temperature for approx. 15 hours.

You can also use any of the following to disinfect the device: isopropyl alcohol 70%, ethanol 70%, Microzid; Burazon liquid, Sporicidin or Cidex. After you have disinfected the cuff, rinse it thoroughly with water and leave it to dry at room temperature

CAUTION
• Danger of electric shock •

Always disconnect the device from your PC before cleaning it.

• Damage to the device •

Do NOT use any disinfection agents that contain phenol and peroxide for disinfecting the surface of the device!
If any fluid has entered the device, then it should only be used again after having been checked and approved by the Service Department.

10.3 Functional check, Maintenance, STC and MTC

10.3.1 *Functional check, Maintenance*

Prior to using the device, manually check the device for any mechanical damage.

If you notice any damage or functional errors, which may endanger the safety of the patient and user of the device, then you should only use the device again after it has been repaired.

10.3.2 *Safety- and Measurement- technical check*

The PHYSIO-PORT is a measuring device in accordance with the German 'Medical Device Code - Operation V' ('MP Betreib V') § 11/ Appendix 2. As a result, the device must undergo a safety technical check and measurement technical check every 2 years. The first of these checks should take place on the date indicated on the calibration mark.

10.4 Calibration mode

To check for example for any leakages in the pneumatic cycle, the PHYSIO-PORT Recorder can be switched into a calibration mode:

- Connect the pump ball over the T-piece between the supplying tube and cuff.
- Roll up the cuff tightly.
- Switch the device off and on quickly.
- Wait until the display shows the time.
- Press the **INFO** button 3 times: the display shows an internal value, which should be between 25 and 100.
- If the displayed value is outside this range, then the PHYSIO-PORT Recorder must be sent away for maintenance.
- Press the **Start/Stop** button:
- The display shows '0' (current pressure in mmHg).
- Create a test pressure of 200 mmHg and measure the decrease in pressure after waiting a minimum of 30 seconds.
- (Decreases in pressure of 3…5 mmHg are normal. Decreases in pressure > 6 mmHg indicate the presence of an unacceptable leakage. In such an event, the PHYSIO-PORT Recorder will need to be sent away for repair).
- You can exit the calibration mode by pressing the **Start/Stop** button.

10.5 Disposing of the device

At the end of its useful life, you need to dispose of tl
described in this manual, including all its accessories
accordance with the disposal regulations for devices
type. If you have any questions in relation to disposa
please contact PAR Medizintechnik GmbH & Co. KG
its representatives.

11. Technical Information

Measuement

Measurement method	oscillometric
Measurement duration	30 – 45 sec. (depends on patient)
Data preservation	unlimited
Measurement intervals	2 – 90 min., programmable
Capacity	Up to 400 measurements

Measurement range

Systole	60 – 260 mmHg
Diastole	40 – 220 mmHg
Heart rate	35 – 240 beats/min.

Cuffs

Connection	Metal locking device
Size	available in various sizes
Cuff pressure	300 mmHg maximum, adjustable

Display/operation controls

Patient display	LCD (measurement values, error codes)
Operation controls	Keypad (Start/Stop, Day/Night, Info)

Interfaces

PC connection	digital interface (RS-232) / USB via adapter

Other

Dimensions (L x W x H)	10.5 cm x 8.0 cm x 2.7 cm
Weight	190 g (incl. batteries)
Operating temperature	+10° to +40°
Transport and Storage temperature	-20° to +70°
Rel. humidity	15 - 85 % (non-condensing)
Air pressure	700 - 1060 hPa
Power supply	2 batteries (type Mignon AA, alkaline) 2 NiMH rechargeable batteries (type Mignon AA, 1500mAh)

12. Charger

If the recorder is powered by rechargeable batteries (4 of them are shipped with the equipment), they should be recharged immediately after use (24 hours). Use only the original charger supplied. It consists of an AC power adapter and the charging unit itself.
Check that the voltage ratings on the nameplate of the charging unit match those of your local power line. Connect the cable of the AC power adapter to the charging unit and plug the AC power adapter into the wall outlet.
Insert 4 or 2 batteries, observing their polarity. To charge only 2 batteries, insert them in the two compartments on the right or on the left.
The batteries take up to 3 hours to recharge.
Once the batteries are inserted, battery symbols will appear in the charger display where each symbol corresponds to one of the charger compartments (Fig. 2). During the charge cycle, the corresponding bar in the battery symbols blinks. Note: If the battery symbols and bar do not light up, only one battery may be inserted or the batteries are inserted the wrong way round.
When the batteries are charged, the bars are permanently illuminated. The charging unit now trickle-charges the battery to compensate for self-discharging.
The battery temperature is monitored in the charger. When the temperature is too high, the bar in the battery symbol is permanently illuminated and the charger switches to trickle-charging.
If the batteries are correctly inserted and the displayed battery symbols show no bars, the charger has identified a battery problem. The charging current to the compartment concerned will be cut off. Remove the battery and discard, observing the applicable waste disposal regulations.

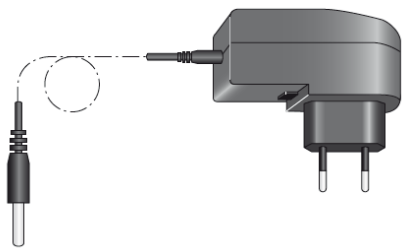


Figure 58: AC power adapter

CAUTION
• Equipment damage, risk to patients •

The charger is not a medical device. It must not be used in the patient environment .

The contact surface of the NiMH batteries and of the charger must always be kept clean.

The charger is to be used indoors only and must be protected against oil, grease, aggressive detergents and solvents to prevent damage.

If the charger is damaged in any way, e.g. after a drop or when the mains pins are bent, the local authorized dealer must be contacted immediately.

High temperatures affect the charging process. Ideally, the room temperature should not exceed 40 °C (104 °F).

After quick charging, please wait for some minutes before another quick charge. Otherwise the temperature sensors will not function correctly.

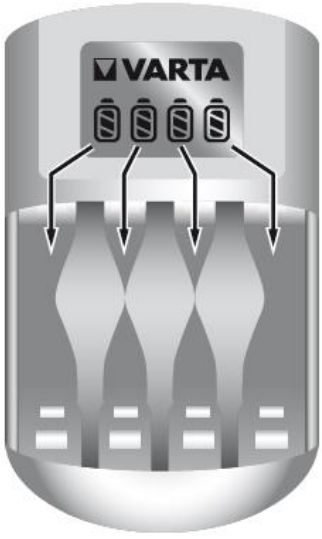


Figure 59: Battery symbols and bars

13. Delivery overview

13.1 Standard delivery

Please note the latest accessories list!

- **PHYSIO-PORT recorder** (Part no: **S185**)
- **Connection cable, USB Interface cable** (Part no: **A867)**
- **Battery charger** (Part no: **A2093**)
- **Rechargeable NiMH battery (4 pcs)** (Part no: **A2004**)
- **Carrying bag** (Part no: **A2206**)
- **Belt for carrying bag** (Part no: **A981**)
- **Blood pressure cuff for adults, standard**, Size M, for circumference between 24..32cm (Part no: **A2524**)
- **User manual (A8135)**
- **CD, Physioportwin**, analysis PC Software (Part no: **A8139**)

13.2 Optional accessories

The optional accessories can be ordered from the manufacturer.

- **User manual (A8135)**
- **Connection cable, USB Interface cable** (Part no: **A867)**
- **Battery charger** (Part no: **A2093**)
- **Rechargeable NiMH battery (2 pcs required)** (Part no: **A2004**)
- **Carrying bag** (Part no: **A2206**)
- **Belt for carrying bag** (Part no: **A981**)
- **Blood pressure cuff for adults, small,** Size S, for circumference between 17…26 cm (Part no: **A2523**)
- **Blood pressure cuff for adults, large**, Size L, for circumference between 32..42 c (Part no: **A2525**)
- **CD, Physioportwin**, analysis PC Software (Part no: **A8139**)