

User manual

PhysioPortWin

PC-Software for
Ambulatory Blood Pressure Monitor (ABPM)



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Revision History

| Revision | Date | Remarks |
|----------|---------|-----------------|
| Α | 2017-07 | Initial release |



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 user manual is not subject to any change service. The state of the latest revision is available from the manufacturer.

1.2 Conformity of the product

The product PHYSIO-PORT bears the CE marking CE-0482 indicating It's 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. The MD-Code for the software is 1111 and GMDN-Code: 57967.

1.3 Identifier

The quality assurance system used by PAR Medizintechnik GmbH & Co. KG in all the company facilities complies with standard EN ISO 13485.

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

CAUTION

Makes you aware for hazard or a hazardous situation. Ignoring these instructions may result in patient, environmental, and third-party injury, as well as failure of the PhysioPortWin software.



2. Product information

2.1 Intended use

The software is intended to configure long-term blood pressure measurement devices from the type of PHYSIO-PORT and TONOPORT, as well as the management and evaluation of such measurements. It provides the possibility to program measurement devices for a long-term measurement with defined parameters like number of measurements, time between measurements, inflation pressure etc. The software can read out data of a long-term measurement from the device and store these data in an internal database. The user can manage any number of patients and long-term measurement with the database. Stored data can be evaluated by click to different criteria. The results of an evaluation are presented in a graphical way and support the physician with the diagnosis of diseases, in particular of the cardiovascular system.

The software is intended for the use with NIBP devices from the type of PHYSIO-PORT and TONOPORT. The use of the software with other NIBP devices or modules is not allowed.

The software provides a GDT interface for the connection to a hospital information system (HIS). The software is intended to be uses on computers that are using a Windows operation system.

The intended patient populations as well as indications and contraindications are equal to the intended use of the long-term blood pressure measurement devices from the type of PHYIO-PORT and TONOPORT.

2.2 Product relevant laws, regulations, and standards

- Council Directive 93/42/EEC
- DIN EN 62304: Medical device software software life cycle processes

2.3 Technical data

Operating system: Windows XP, Windows Vista, Windows 7, Windows 8, and Windows 10 each

as a 32 bit/64 bit version

Processor: at least 1.6 GHz Dual Core

Random access memory: at least 2 GB
Disk space: at least 250 GB

Screen resolution: at least 1.024 x 768 Pixel Connections: USB (1.1, 2.0 or 3.0)

Warning

• Safety for patients, users and other persons • Equipment may be connected to other equipment or to parts of systems only when the connection is without hazard. The used computer has to comply with the standard IEC 60601-1 or IEC 60950-1.



3. Installation and commissioning

3.1 Installation

Insert the PhysioPortWin CD in the CD ROM drive.

The installation starts automatically, if the CD drive does not start automatically follow these steps:

- open the Windows explorer
- choose the CD drive
- double click on "setup.exe"

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



Figure 1: Selection menu of the installation language

After selection of the language starts the software installation.



Figure 2: Software Installation



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

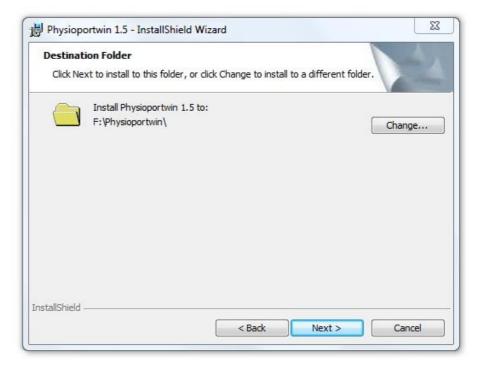


Figure 3: Destination Folder

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

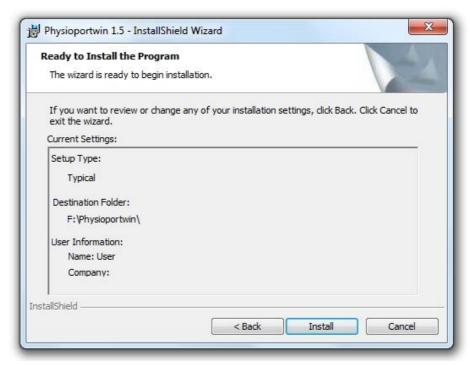


Figure 4: Display of the installation settings



Click Finish to complete the software installation.



Figure 5: End of the software installation

3.2 Activation of the program

You have to activate the software after the installation. The software is usable up to 14 days without activation and afterwards the software can only be used with constraints. The license file can be requested by click on "Order license file". Therefore you have to enter the software serial number and the file "license.dat" will be generated. The file will be send via email to info@par-berlin.com.

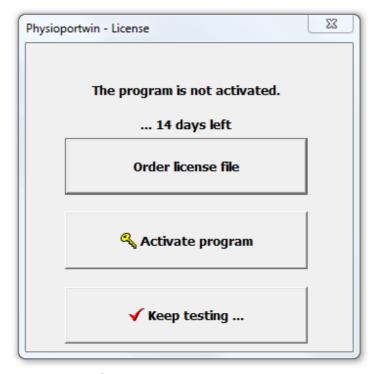


Figure 6: Menu for the program activation and license request



You will receive the activation file "PAR_License.dat" via email. Now click on "Activate program" to activate the software (see Figure 6). Choose the received file and open it to finish the activation.



Figure 7: Mask for the input of your serial number

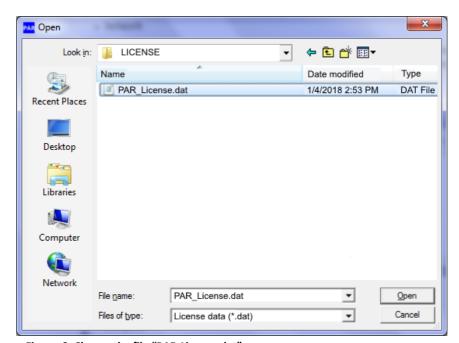


Figure 8: Choose the file "PAR-License.dat"



3.3 Settings

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

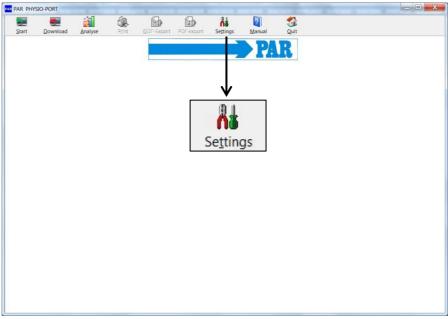


Figure 9: Settings

The different settings are split on four tabs.

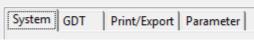


Figure 10: Tabs for program settings

3.3.1 *System*

All default settings of the PHYSIO-PORT system are made on this tab.

It's recommended detecting the connected recorder automatically.

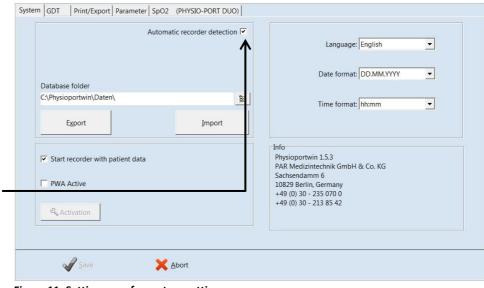


Figure 11: Setting page for system settings

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



Figure 12: Recorder connection



This setting allows starting the recorder with or without patient data.

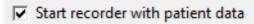


Figure 13: Enter of patient data

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



Figure 14: Database folder

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

database.

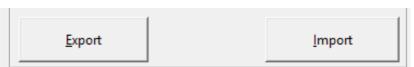


Figure 15: Import and Export of database

CAUTION

· Lost of data ·

The restoration [IMPORT] of the database overwrites the actual database! It's recommended saving the actual database **before** importing the database.

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

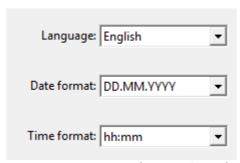


Figure 16: Language, Date format and Time format



3.3.2 *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 tab all settings can be set to connect the software with IT systems via GDT interface.

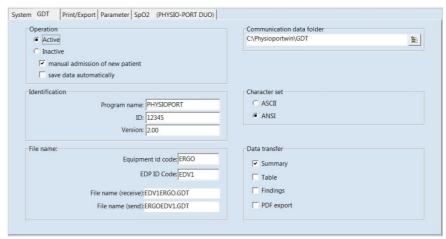


Figure 17: GDT settings

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.

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 HIS 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.

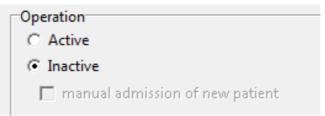


Figure 18: Activation of GDT interface

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).

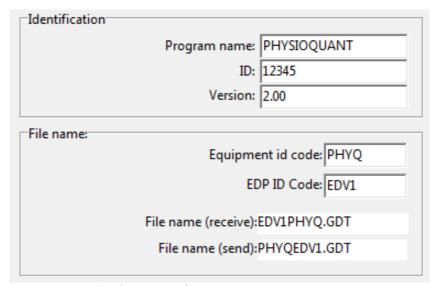


Figure 19: GDT identification and filename

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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.

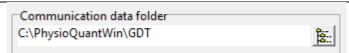


Figure 20: Folder for communication data files

Character set:

Actual used character set can be selected (ASCII or ANSI). It concerns the representation of äöüß during the data transfer. Data transfer: Prior selection will determine which data is transferred to general practice IT system. If you activate the PDF export, the GDT file will contain a link to the

generated PDF file.

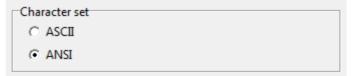


Figure 21: Character set



Figure 22: Setting of data transfer



3.3.3 Print/Export

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

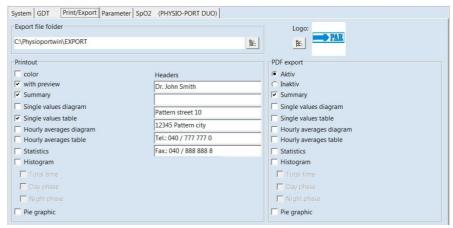


Figure 23: Setting page for print and export of analysis

Print out:

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

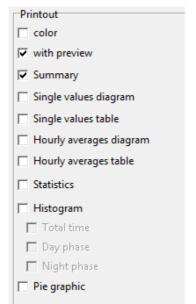


Figure 24: Configuration of print out

Entered headers are printed on every printed sheet.



Figure 25: Headers for print out



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>^<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.

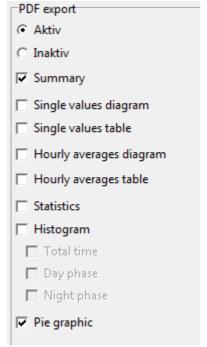


Figure 26: Configuration of PDF Export

Selection of folder for export files.



Figure 27: Folder for export file



3.3.4 Parameter

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

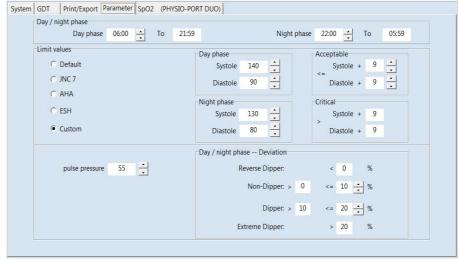


Figure 28: Configuration of parameter

Day and night phase: Default values can be set.

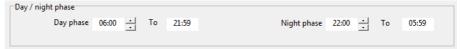


Figure 2: Default values for day and night phase

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.

Limits for the nightly pressure drop can be defined.



Figure 30: Limit values

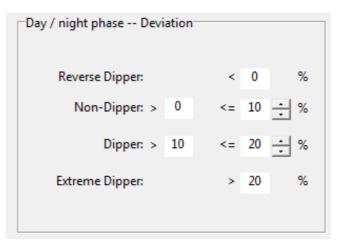


Figure 31: Setting of dipper limit values



3.4 Network installation

The software PhysioPortWin is network-compatible and allows the central storage of patient information and measurements (i.e. on the server). This information can then be accessed from all workstations.

Therefore you have to set and release a directory on the central server. You have to connect this directory to all workstations.

Additionally you have to install the software on all workstations that will use it.

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



Figure 32: Database folder

4. Start of a long-term blood pressure measurement

4.1 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:

4.2 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.

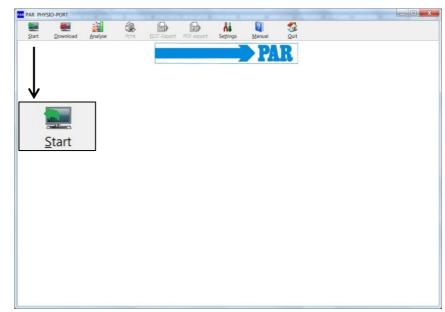


Figure 33: Main menu with the Start button



4.3 Selecting a patient

4.3.1 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 F): Select the required patient, by double clicking on the relevant line.

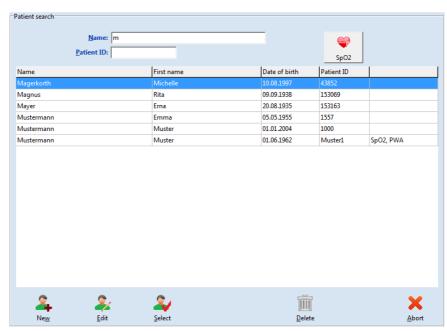


Figure 34: Selecting a patient

4.3.2 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]:

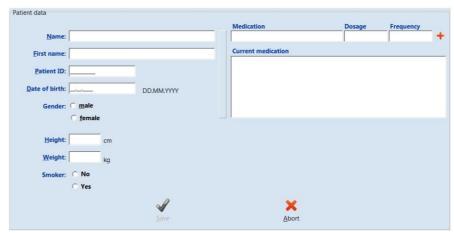


Figure 35: Adding of a new patient

4.3.3 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!



4.4 Programming recorder

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

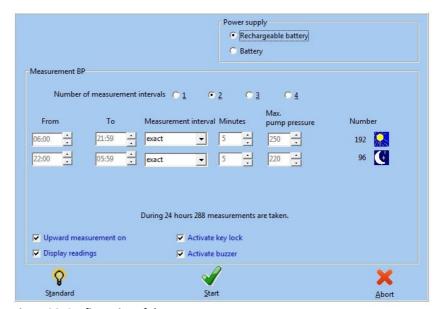


Figure 36: Configuration of the measurement

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.

Time frame for the blood pressure measurement:

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 maximum 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.

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

Activate inflation The inflation measurement method is activated (Inflation

measurement: Measurement Technology, IMT)

Activate beeper: The internal beeper (optional) can be switched on and off. If the

beeper is on, than an acoustic signal sounds when the device is switched on, before the measurement or in case of faulty

measurement.

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

values:

Measurement intervals

 Interval 1
 Interval 2

 (day phase):
 (night phase):

 06:00 - 21:59
 22:00 - 05:59

exact every 15 min exact every 30 min

SpO₂ measurement:

22:00 - 05:59 Interval 2 sec

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.



5. Download

5.1 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:

5.2 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.

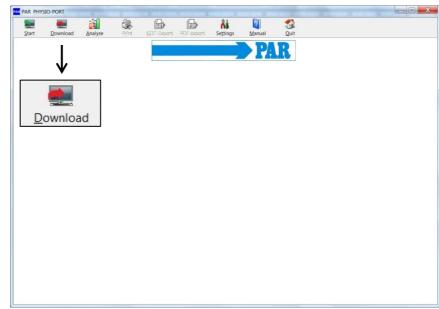


Figure 37: : Main menu with the Download button



6. Analyse

6.1 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.

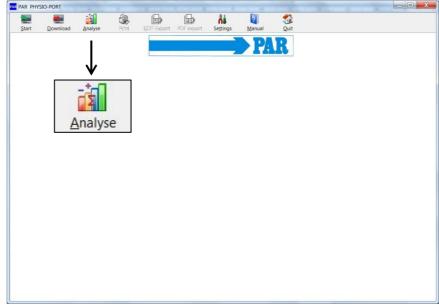


Figure 38: Main menu with the Analyse button



6.2 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.

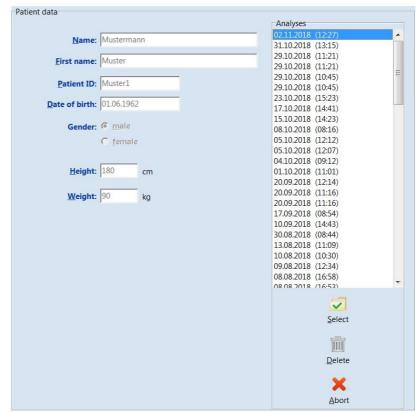


Figure 39: Selection of analysis



6.3 Representations

6.3.1 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.

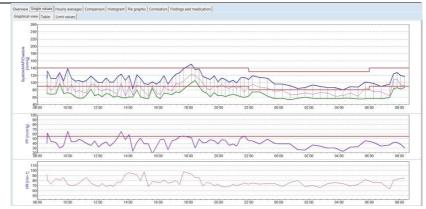


Figure 40: Graphical single values

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 | | |
| 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 | | |
| 07.09.2015 13:02 | 101 | 60 | 75 | 68 | | |
| 07.09.2015 13:17 | 115 | 64 | 68 | 77 | | |
| 07.09.2015 13:32 | 124 | 59 | 98 | 77 | | |
| 07.09.2015 13:49 | 106 | 58 | 63 | 92 | | |
| 07.09.2015 14:04 | 120 | 61 | 90 | 96 | | |

Figure 41: 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.

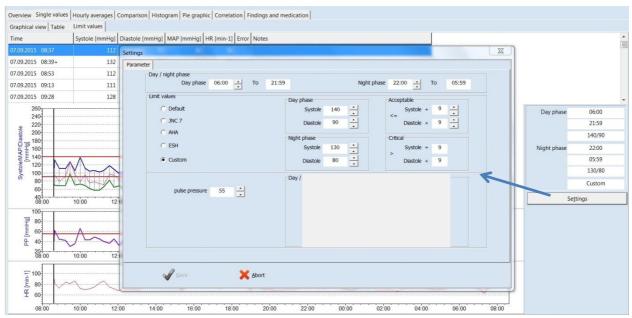


Figure 42: Limit values

6.3.2 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 and clicking again shows the complete evaluation.

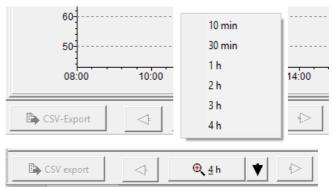


Figure 43: Magnifying glass

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

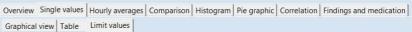


Figure 44: Select representation



6.3.3 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.

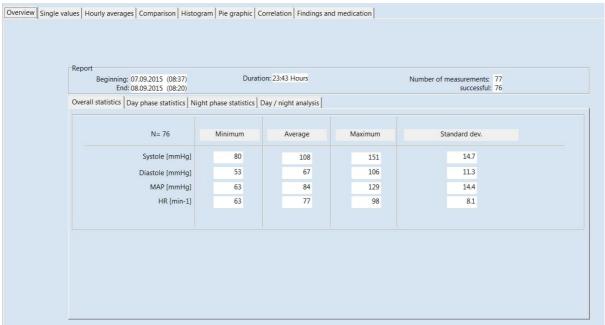


Figure 45: Overview statistics

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

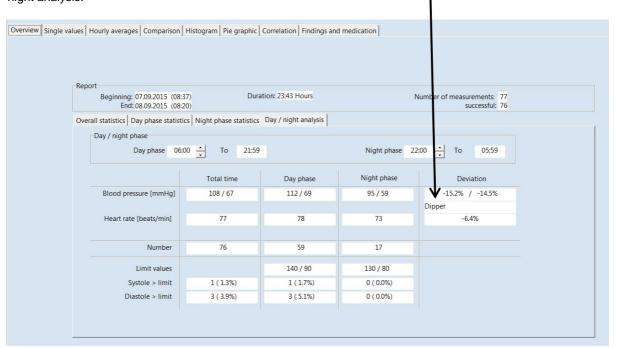


Figure 46: View of a day / night analysis with information about the dipper type of the patient



6.3.4 Hourly mean values

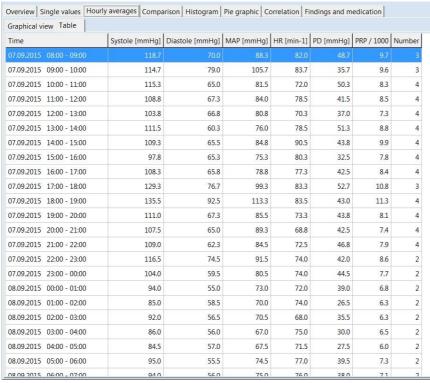


Figure 47: Tabular hourly mean values

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

6.3.1 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 48: Comparison of two measurement series



6.3.2 Histogram

The histogram presentation of measured values is possible.

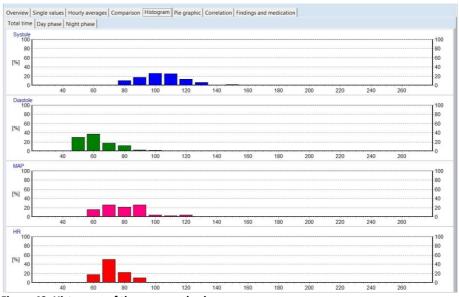


Figure 49: Histogram of the measured values

6.3.3 Pie graphic

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

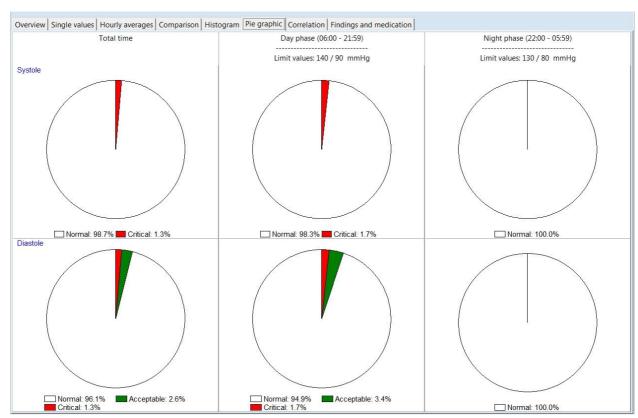


Figure 50: Presentation of the values a pie graphic



6.3.4 Correlation

This diagram shows the correlation of diastolic to systolic blood pressure. Each dot equates to a measurement.

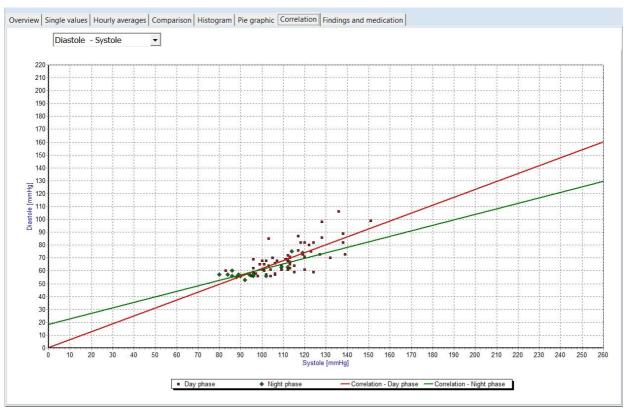


Figure 51: Correlation of blood pressure values



6.4 Additional buttons

6.4.1 Report and medication

This tab enables the generation of a medical report according to a long-term measurement. This information is printed on the summary page and can be provided to a HIS, if activated. Additionally the medication is displayed and can be edited.

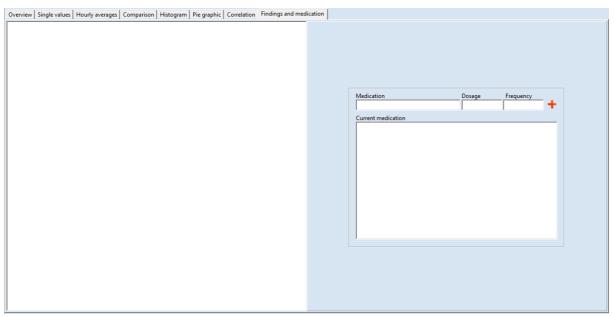


Figure 52: Tab for the report and the medication

6.4.2 Print

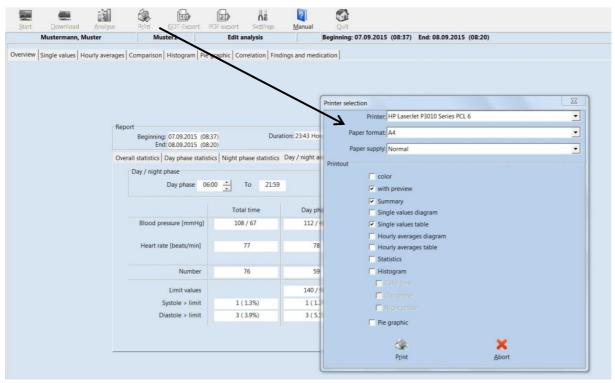


Figure 53: Selection of pages



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'

6.4.3 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".

6.4.4 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.

6.4.5 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.