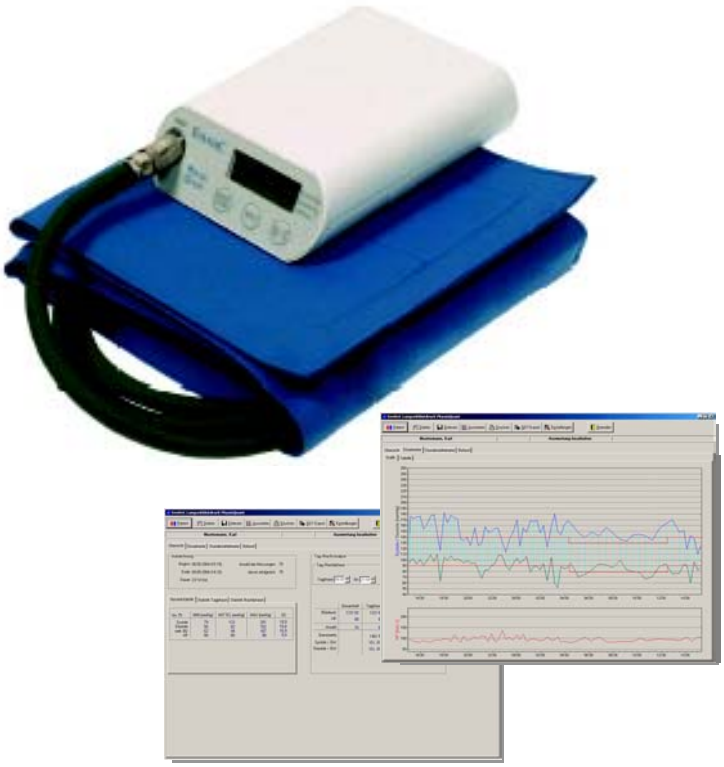
PhysioQuant

Ambulatory Blood Pressure System

User-Manual



ENVITEC

User-Manual

PhysioQuant Ambulatory Blood Pressure System

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

This manual is subject to updates by EnviteC-Wismar GmbH.

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EU - Conformity Statement

We declare with sole responsibility,
that the product:

System for long-term Blood Pressure Reading

PhysioQuant **45-00-0500**

complies with the basic requirements according to appendix I of the Regulations of the Council on Medical Products of 14th June 1993 (93/42/EWG). The product was classified according to appendix IX of the Regulation 93/42/EWG as

Class **IIa**

CE mark awarded:

CE 0123

Issued by:

ENVITEC - WISMAR GMBH
Alter Holzhafen 18
D-23966 Wismar
Germany

Place, Date: Wismar, 10-06-2004

Authorised signature: .....

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Contents

1 General Remarks / Symbols

This symbol means: please consult the manual. It refers to things to which you should pay careful attention when using the device.

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.

2 Safety Instructions and Use

- The product **PhysioQuant** carries the CE mark **CE-0123** in accordance with European Council Directive 93/42/EEC in relation to medical devices and complies with the fundamental requirements stated in Appendix I of this Directive. The device has an internal power source and comes within Class IIa (MDD).
- The device has an application part of the type 'BF'.
- Standard EN 60601-1 'Medical electrical equipment, Part 1: General Requirements for Safety' is complied with, as well as the immunity requirements of standard EN 60601-1-2 'Electromagnetic Compatibility - Medical Electrical Equipment'.
- The device is interference-free in accordance with EN 55011 - Class B.
- The CE mark only includes those components described in the delivery overview.
- This manual forms part of the device. It should always be kept near to the device. Correctly observing the manual ensures that the device will be used in an appropriate manner and for the purpose it is intended. It will also ensure the health and safety of users and patients dependent on it.
- Please read through the whole manual carefully, since information that is relevant to several sections is only provided once.
- The printed text of this manual is in accordance with the version of the device, as well as the relevant safety instructions standards, at the time that this manual was printed. All industrial property rights are reserved in relation to any devices, circuits, processes, software programs and names described in this manual.
- The quality assurance system used by EnviteC-Wismar GmbH in all the company facilities complies with standards EN ISO 9001 and EN ISO 13485.
- 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 EnviteC-Wismar GmbH.
- No warranty claims can be made in the event of any damage as a result of using other inappropriate accessories and consumable materials.

- EnviteC 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 EnviteC, or at locations that have been expressly authorised by EnviteC to carry out such repairs;
  - Devices that have been used in accordance with their manuals.
- **Intended use:**
  PhysioQuant is a manually-operated blood pressure measuring device, carried by the patient for long-term measurement of non-invasive blood pressure. It can be used for adults, children and infants by applying the corresponding cuffs. PhysioQuant must **not** be used for newborn babies and is **not** suitable for use in Intensive Care Units. PhysioQuant can be used to take blood pressure measurements at various intervals for up to 30 hours and is able to store measurement results.
- **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 EnviteC-Wismar GmbH or one of its representatives.
- **Cleaning:**
  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.
- Only clean the PhysioQuant Recorder when it is not connected to another device.

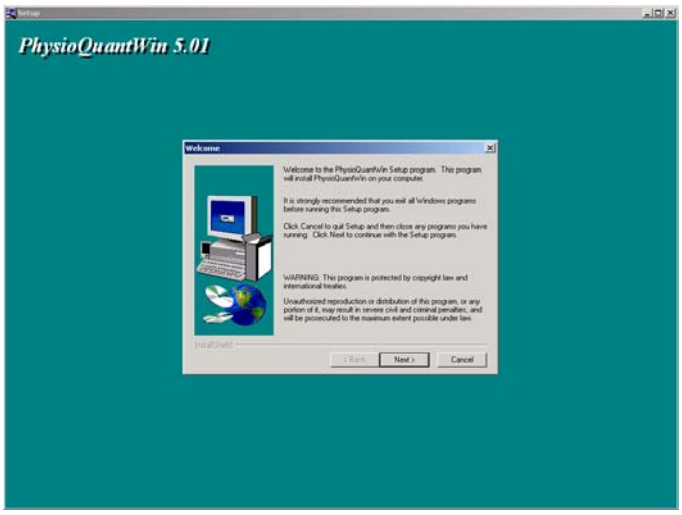
CAUTION!

- The device is not suitable for use in areas where explosions may occur. Such areas may appear as a result of using inflammable anaesthetics, skin cleaning and skin disinfection products.
- The device should only be used together, or in combination with components of other equipment, when you have ensured that this connection does not adversely affect the health and safety of patients and users, or the environment.
- If the information provided with the device is not clear on how to make a safe connection that will ensure the health and safety of patients, users, as well as the environment, then please contact the manufacturer or consult a technical expert. At all times, observe standard IEC 60601-1-1.
- The PhysioQuant Recorder can be connected to, and operated from, a PC on which PhysioQuantWin software has been installed. Please note that no patient should be connected to the PhysioQuant Recorder as long as it is connected to the PC.
- Before using the device on a patient, the user should check that the device functions safely and as intended.
- Users must be familiar with how to operate the device.
- Medico-technical devices should only be used by suitably-qualified or experienced persons, who can ensure that the device is used correctly.
- The device does not contain any components that need to be replaced by users. Never open the casing of the device (please contact the Service Department).

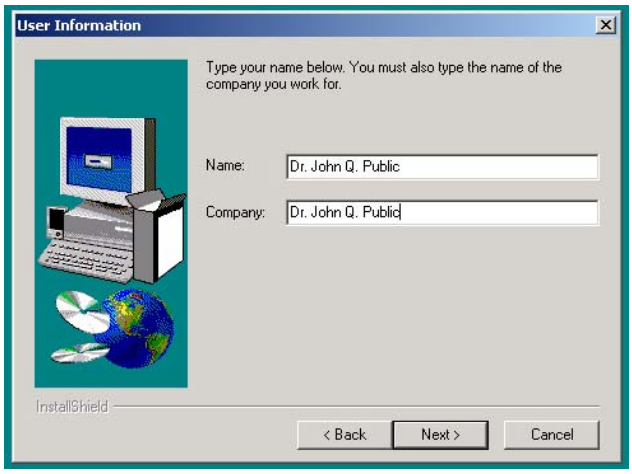
3 Installation

3.1 Software

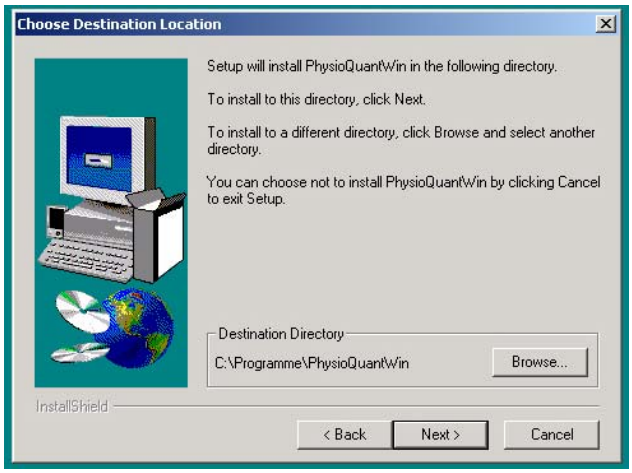
- Put the PhysioQuant CD in your CD-ROM drive.
- If the 'Auto start Function' of your CD-ROM drive is activated, then installation will begin automatically. If not:
  - Open Windows Explorer, select your CD-ROM-drive and double click on **setup.exe**.
- The installation wizard appears:



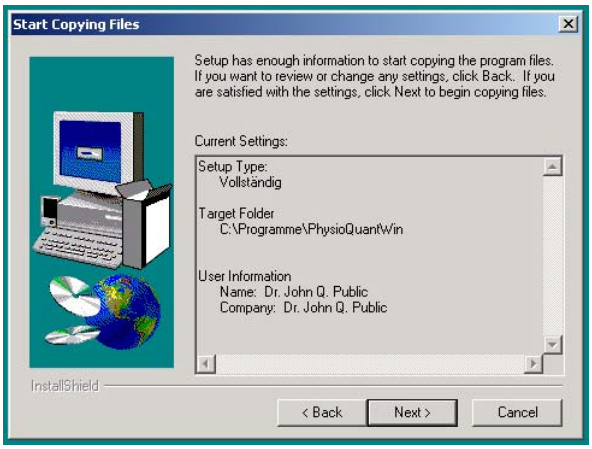
- Confirm that you are to start the installation by clicking on **[Next]** and follow the on-screen instructions.



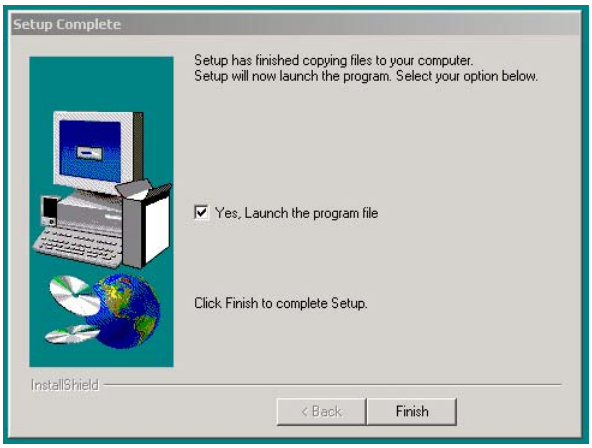
Enter your name and that of your practice and confirm with **[Next]**.



The programme will normally be installed under your standard program directory. You can change this location via **[Browse]**.



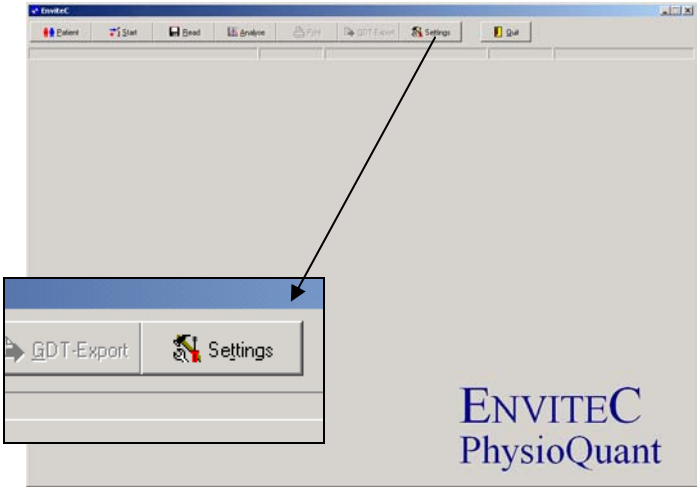
All settings are summarised before installation commences. After confirming with **[Next]**, the copy and installation process begins.



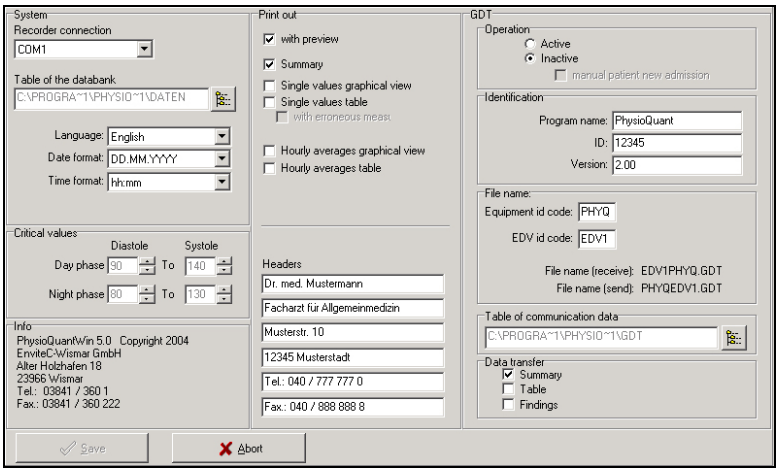
Once the installation has been completed, the PhysioQuant programme starts automatically and the required settings can be selected.

3.2 Settings

After the programme has started, the main screen will be displayed.
To configure the software, click on the 'Settings' icon to open the Settings menu:

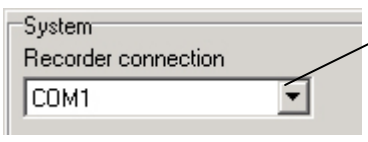


Settings menu:



SYSTEM:

- Setting the serial PC interface, to which the PhysioQuant Recorder will be connected:

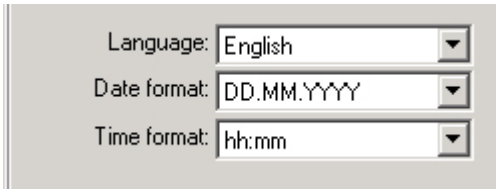


This displays all serial interfaces of the system.

- Setting / changing the folder for the database (also see 3.4 Network installation, page 18)

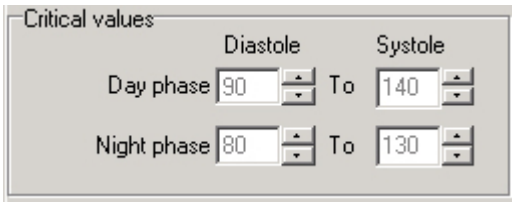
Selecting another folder for the database.

- Setting language, date and time format:



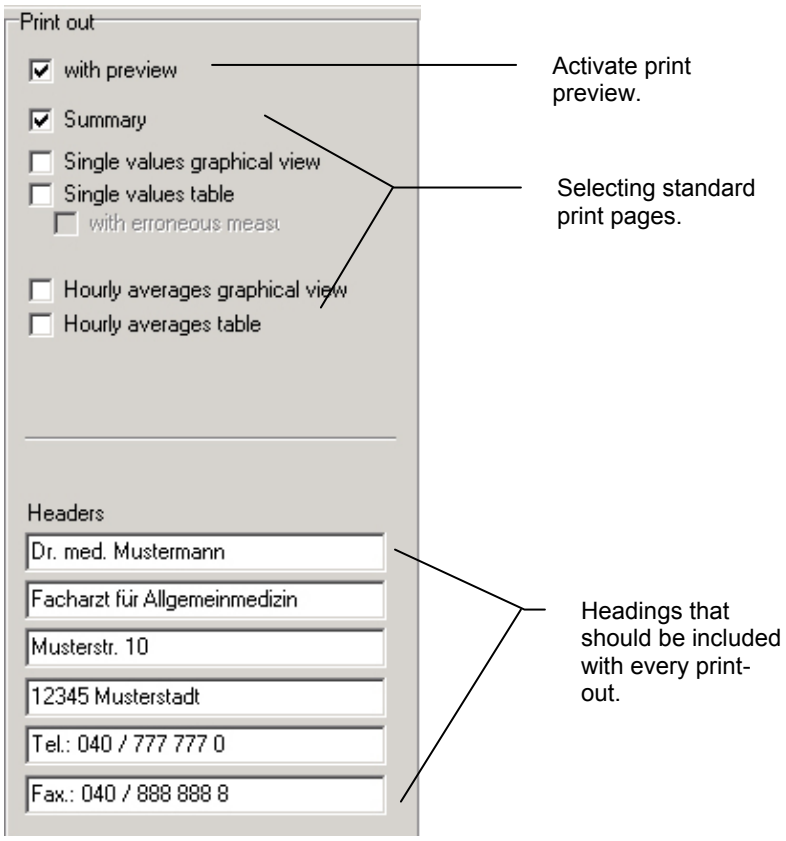
CRITICAL VALUES:

- Setting the critical values for day phase and night phase:



- These critical values will be displayed as lines in the graphic representation of the analysis and will be part of the statistical calculations.

PRINT:



GDT:

The description of the GDT interface and the required settings can be found in Section 3.5 GDT interface,18.

3.3 Attaching the connecting 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 special connecting cable.

This special connecting cable is connected to a free serial interface of the PC ('COM x') via the 9-pin DSB port.
If the recorder only has a USB connection, then the connection can also be made by using one of the commercially available USB-to-serial converters.
Please contact your specialist dealer for more information.

The cable also needs to be plugged into the 6-pin, black port, which is located at the back of the casing of the device. Please ensure that the plug is in the right position when connecting it ('nose' up):

3.4 Network installation

The PhysioQuantWin 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 programme installation is then carried out on all workstations that will use the PhysioQuant software (as described in Section 3 Installation, page 11).

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

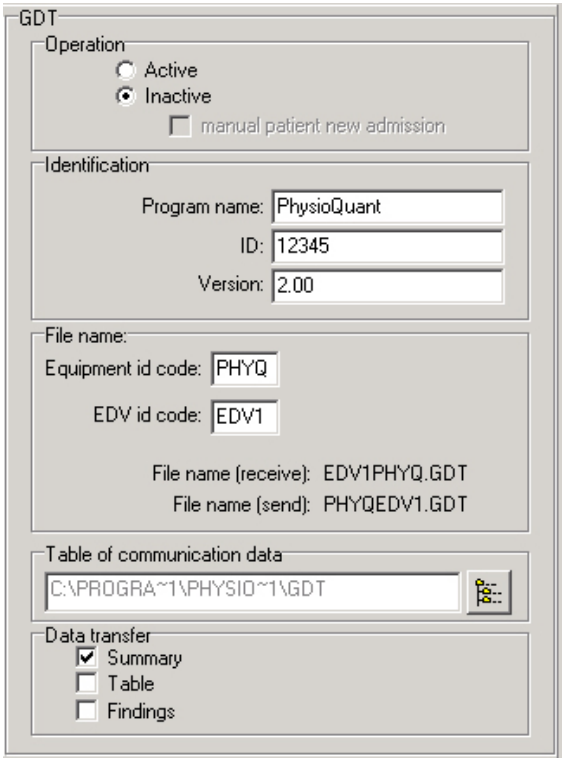
3.5 GDT interface

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 PhysioQuantWin 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.

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 programme whether the defined GDT data is available and processes it. If no data is found, then a 'normal' programme start will take place.

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 PhysioQuant 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 PhysioQuant system during GDT data transfer.

File names
The file names that are used for the communication between general practice IT systems and PhysioQuant software should be entered in the '**File names**' field.
File names consists of a **device identification code** (1 - 4 characters), e.g. PHYQ, and a **EDP identification code** (1 - 4 characters) for the general practice IT systems, e.g. EDP1.
Both these identification codes are then used to create file names, which will always have the extension *.GDT.

Directory 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).

NB: 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.

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

Example Short summary (one line)

```
LZBDM: Day 108/ 67/ 78 -  Night 0/  0/ 78 = -100/-100/-100 %
```

Example Table

24 h BPM	Day phase 06:00-21:59	Night phase 22:00-05:59	Difference Day/Night phase
Mean values:			
Ps[mmHg	108	0	-100%
Pd[mmHg	67	0	-100%
HR[P/min	78	0	-100%

4 PhysioQuant Recorder

4.1 Operation controls

1 **Cuff connection**

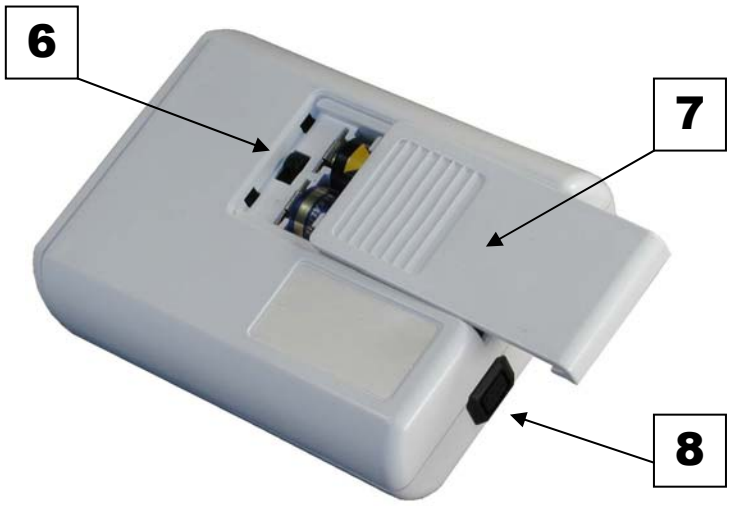
2 **Start/Stop button** to delete additional measurements and to interrupt a measurement in process.

3 **Info button** to display the most recently measured values. The following values will be displayed respectively:

- Systolic value 'S/mmHg'
- Diastolic value 'D/mmHg'
- Pulse frequency 'HR/min-1'.

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

5 **LCD display** to display all information.

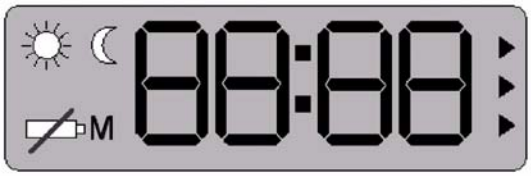


6	**On/Off switch**
7	**Battery compartment lid**
8	**Connecting port for PC connecting cable**

4.2 Symbols on the device

	Warning, please observe the manual
	Data export / data import
	Application part type BF (defibrillation-proof)

4.3 LCD display with all symbols and display options



M

- Flashes for every detected oscillation
- Displayed constantly when measurement data has 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 selected

4.4 Power supply

The PhysioQuant Recorder requires either two nickel metal hydride rechargeable batteries, or two alkaline batteries.

When starting the recorder via the PhysioQuantWin software, please ensure that the relevant power source has been selected (see 6.6 Programming the recorder, page 30)

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 30 hours of operation or 200 measurements.

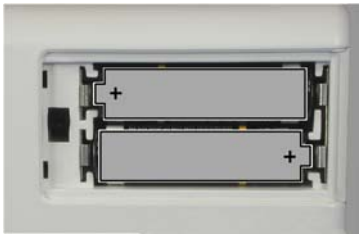
Battery capacity reduces in line with increased use. If the capacity of the two fully-charged rechargeable batteries clearly falls below 24 operating hours, then you need to replace them.

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

4.5 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:

Please ensure that the batteries are inserted correctly!



4.6 Function control

The PhysioQuant 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

4.7 Connecting 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.

5 PhysioQuant Cuffs

Various cuff sizes are available for the PhysioQuant (standard, large and children size).

Please select the correct cuff size (see printed text on the cuff)

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.

Replace the cuffs at regular intervals. Damaged Velcro fasteners may lead to incorrect measurements.

6 Commencing Long-Term Blood Pressure Measurement

6.1 Connecting the recorder

Connect the PhysioQuant Recorder to the PC (see 3.3 Attaching the connecting cable to the recorder,17) and switch on the recorder.

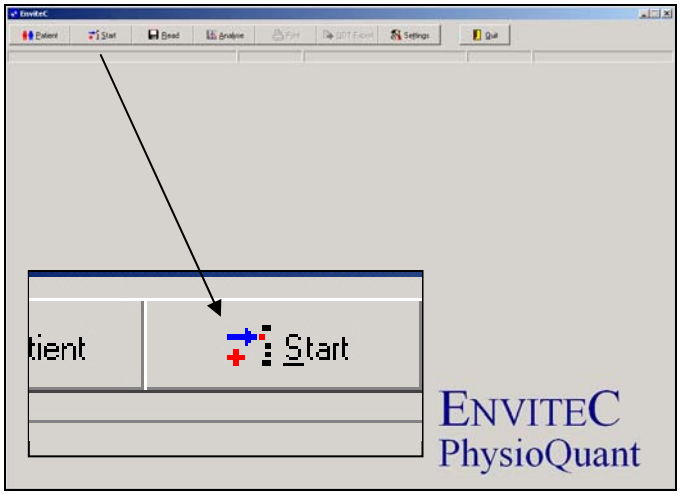
The on/off switch is located beneath the lid of the battery compartment. (see *4 PhysioQuant Recorder*

No. 6, page 21)

The recorder display will show **PC** >
>
>

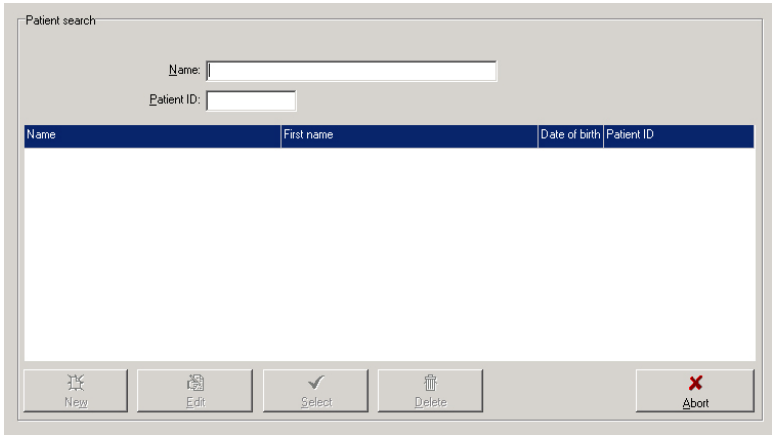
6.2 Starting the programme

After the PhysioQuant software has started, the main screen appears. To programme the recorder, click on the 'Start' tab to open the relevant menu:

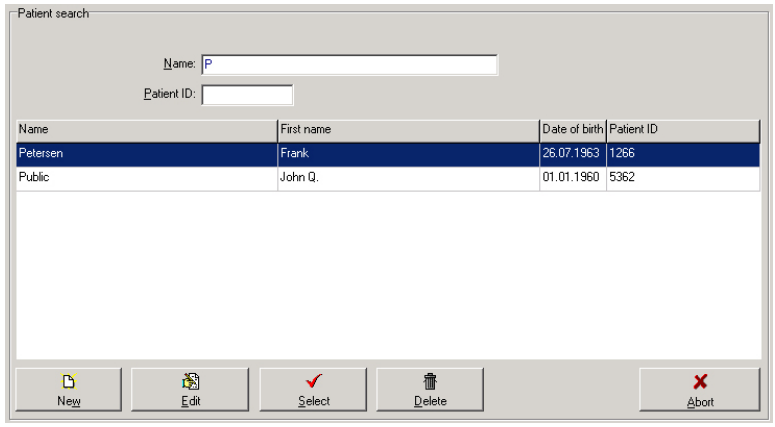


6.3 Selecting a patient

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 **P**):

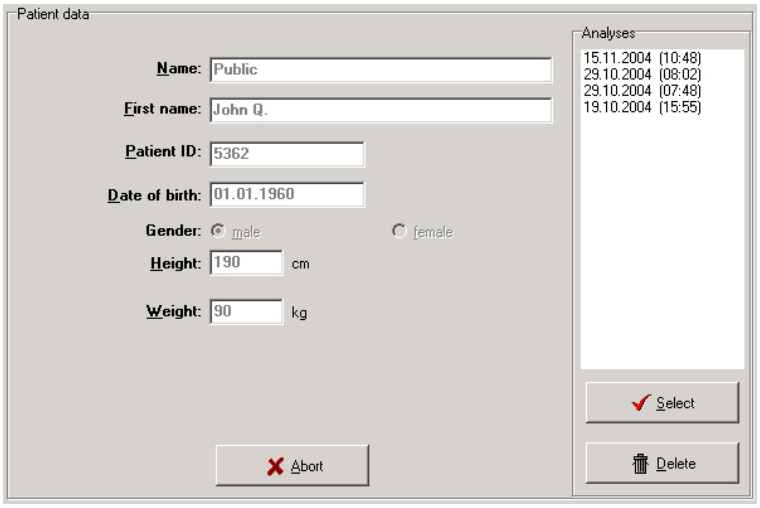


Select the required patient, by double clicking on the relevant line.

6.4 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]**:



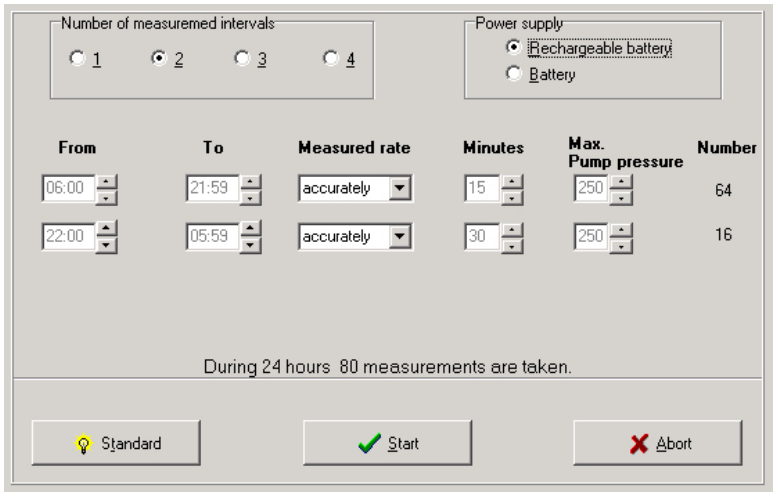
6.5 Editing patient data

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!

6.6 Programming the recorder

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



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 90 minutes.

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

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

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

2 measurement intervals			
Interval 1 (day phase):			
06:00 - 21:59	Exact	every 15 min.	250 mmHg
Interval 2 (night phase):			
22:00 - 05:59	Exact	every 30 min.	250 mmHg

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.

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

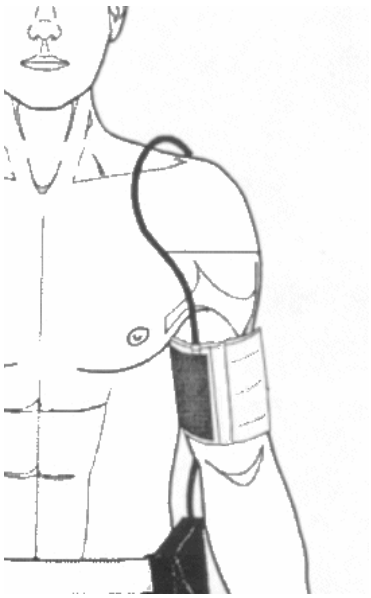
6.7 Attaching the cuff and the recorder

CAUTION!

The PhysioQuant 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 PhysioQuant Recorder and place it in the carrier bag.

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 PhysioQuant (see 4.7 Connecting the cuff to the recorder, page 26).

Ensure that the tube cannot become disconnected while the measurement is being taken.

6.8 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: 

After a brief moment, the device will inflate the cuff. 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.

6.9 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 PhysioQuant 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.

Important guidelines for patients:

CAUTION!

- 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.

6.10 Important measurement information

For the first measurement, the device will inflate the cuff to approx. 160 mmHg (starting pressure). For subsequent measurements, the inflation pressure will be 25 mmHg 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' (200 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.

6.11 Button functions

Recorder buttons have the following functions during long-term blood pressure measurements:

is used too begin and end a measurement.

is used to display the most recent measured values or the most recent error message.

is used to manually switch the measurement intervals from the day to night phase, and vice versa.

Note:

You can only manually switch between day and night phase when **2 measurement intervals only** have been programmed via the PhysioQuantWin software when the starting sequence of the recorder was commenced.

If more or less measurement intervals have been programmed, then the Day/Night button has no effect on the measurement intervals.

7 Importing Recorder Data after Measurements

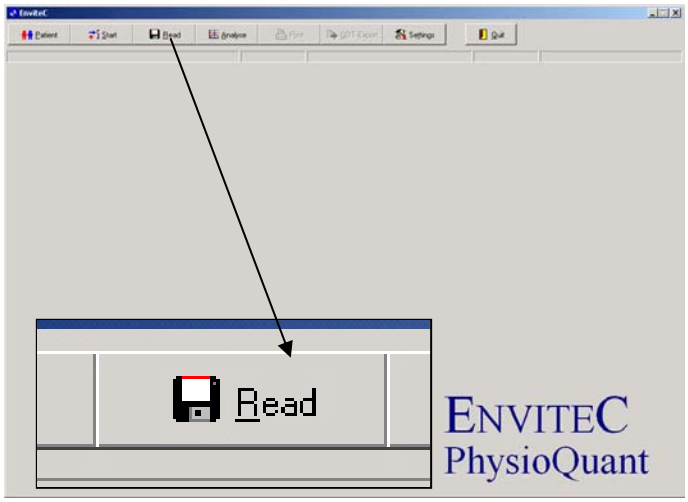
7.1 Connecting the recorder

Connect the PhysioQuant Recorder to the PC (see 3.3 Attaching the connecting cable to the recorder, 17) and switch on the recorder.

The recorder display will show **PC** >
>
>

7.2 Starting the programme

After the PhysioQuant software has started , the main screen appears. To import data from the recorder, click on the **[Import]** tab to open the relevant menu:

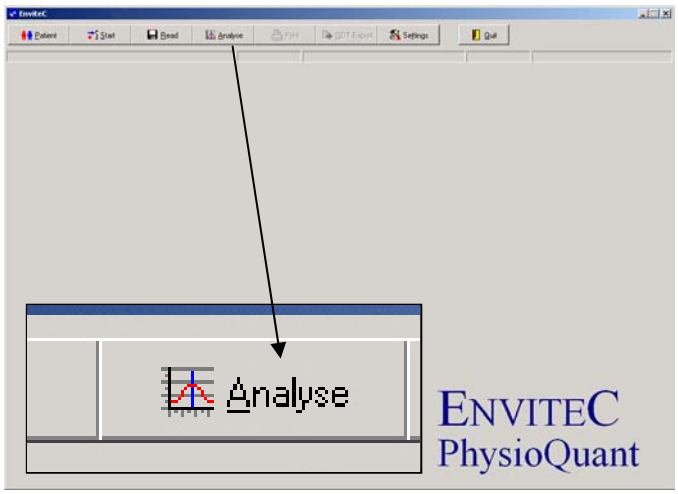


The measurement values are imported from the recorder and assigned to the relevant patient.
The graphical representation of the measurement results is also displayed (see 8.5 Single-value graph, page 40).

8 Analysis of Measurement Results

8.1 Starting the programme

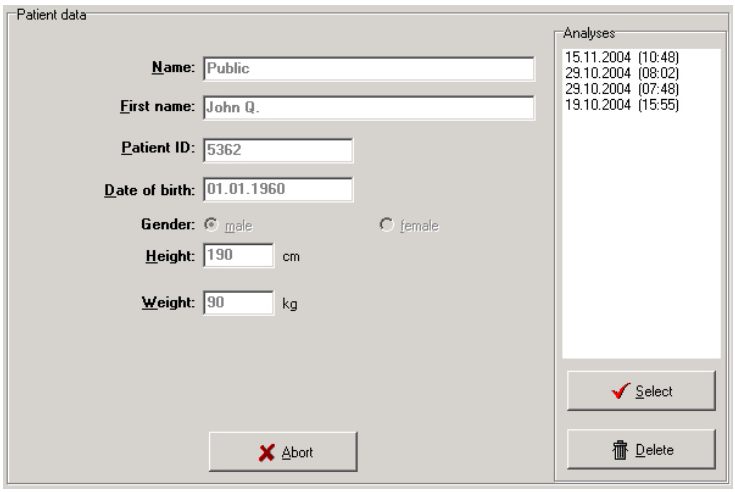
After the PhysioQuant software has started, the main screen appears. To request saved measurement results, click on the **[Analysis]** tab to open the relevant menu:



8.2 Find/delete measurement results

The selection window of the patient database is displayed. Select the required patient (see 6.3 Selecting a patient, page 28).

The measurement result selection window appears for those patients whose data have been stored in the database.

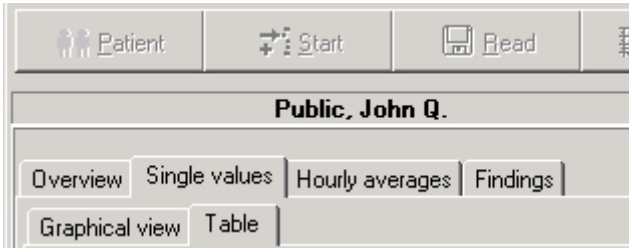


You can request the relevant saved measurement results by double clicking on the relevant data in the selection window.

Deleting measurement results
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.

8.3 Representation

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



8.4 Overview

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.

8.5 Single-value graph

This graph displays the results of all individual measurements. The set critical values for the day and the night phase (see 3.2 Settings, page 14) are displayed as red lines.

8.6 Single-value table

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.

Deleting individual measurements
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.

8.7 Hourly mean values graph and table

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

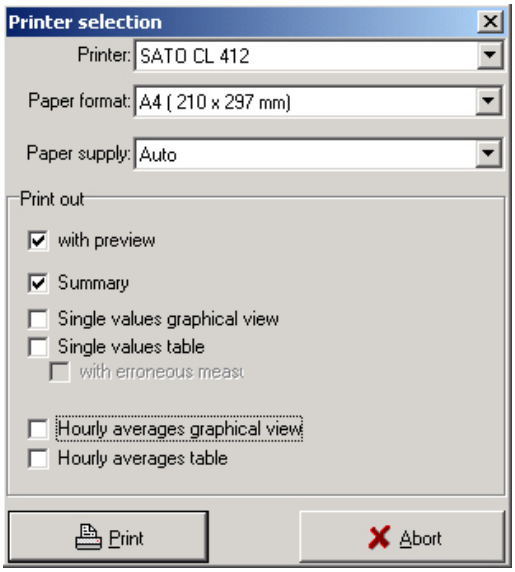
8.8 Findings report

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.

8.9 Printing

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

The size of the printout can be determined on an individual basis. You can define a standard format under 'Settings' (see 3.2 Settings, page 14).



The integrated printing preview allows you to view the selected pages prior to printing.

8.10 GDT export to general practice IT systems

If the PhysioQuant 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.

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 faultysealing.

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). PhysioQuant 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 Scope of Delivery

PhysioQuant System **45-00-0501**

Includes:

PhysioQuant, standard adult blood pressure cuff, PhysioQuantWin software, interface cable, carrier bag, belt and manual.

PhysioQuant Recorder **45-00-0502**

Includes:

PhysioQuant, standard adult blood pressure cuff, carrier bag, belt and manual.

11 Accessories and Spare Parts

Standard cuff – Adult	**45-00-0509**
Large cuff – Adult	**45-00-0510**
Cuff – Child	**45-00-0511**
Interface cable	**45-00-0515**
Bag	**45-00-0513**
Belt	**45-00-0512**

12 Cleaning and Maintenance

12.1 Cleaning and disinfection of device surface

CAUTION!

Danger of electric shock
Always disconnect the device from your PC before cleaning it.

- Switch off the PhysioQuant 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.

CAUTION!

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.

12.2 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.

12.3 Cleaning of tubes

- Remove the tube from the device.
- Rub the tubes with a moist cloth (soapsuds). NEVER dip the tube into any fluid.

12.4 Maintenance and validity check prior to any use

- 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.

Measurement technical check

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

12.5 Calibration mode

, To check for example for any leakages in the pneumatic cycle, the PhysioQuant 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 PhysioQuant 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 PhysioQuant Recorder will need to be sent away for repair).
- You can exit the calibration mode by pressing the **Start/Stop** button.

12.6 Disposing of the device

At the end of its useful life, you need to dispose of the device described in this manual, including all its accessories, in accordance with the disposal regulations for devices of this type.

If you have any questions in relation to disposal, then please contact EnviteC-Wismar GmbH or one of its representatives.

13 Technical Information

Measurement	
Measurement method	oscillometric
Measurement duration	30 – 45 sec. (depends on patient)
Data preservation	unlimited
Measurement intervals	2 – 90 min., programmable
Capacity	200 measurements or 30 hours
Measurement range	
Systole	60 – 260 mmHg
Diastole	40 – 220 mmHg
Heart rate	35 – 240 beats/min.
Cuff	
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°
Rel. humidity	30 - 75 % (non-condensing)
Air pressure	700 - 1060 hPa
Power supply	2 batteries (type Mignon AA, alkaline) 2 NiMH rechargeable batteries (type Mignon AA, 1500 mAh)

ENVITEC

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