PHYSIO-PORT UP

Ambulatory Blood Pressure System

Firmware Version 3.0

Operator's Manual

A9951 - ENG Revision C

Note

The information in this manual only applies to PHYSIO-PORT UP, firmware version 3.0. It does not apply to earlier firmware versions.

Due to continuing product innovation, specifications in this manual are subject to change without notice.

Table of Contents

Revision History

This manual is subject to the GE Healthcare change order service. The revision code, a letter that follows the document part number, changes with every update of the manual.

Part No./Revision	Date	Comment
A9951 - ENG Revision A	2017-05	Initial Release
A9951 - ENG Revision B	2022-03-28	Changing of the manufacturer Address
A9951 - ENG Revision C	2023-02-09	Updated for MDR requirements of the PHYSIO-PORT UP device. Update of the order information in Chapter 10, Change of the battery charger

General Information

- The product **PHYSIO-PORT UP** bears the CE marking **CE 0482** (notified body MEDCERT GmbH) indicating its compliance with the provisions of the Regulation (EU) 2017/745 (Medical Device Regulation MDR) about medical devices and fulfills the essential requirements of Annex I of this regulation. The devices have an internal power source and are MDR class IIa devices. The devices fulfill the requirements of the Directive 2011/65/EU of the European Parliament and of the Council and its amending Directive (EU) 2015/863 of the European Parliament and of the Council. The cuffs listed in Chapter 10 are a class I device and fulfill the General Safety and Performance Requirements of Annex I of the Regulation (EU) 2017/745 (Medical Device Regulation MDR). They are marked with the **CE** symbol.
- It has a type BF applied part.
- 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 safety standard for automatic sphygmomanometers 80601-2-30 and 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.
- The product is clinically validated. The validation fulfills the standard ISO 81060-2 “Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type” and the protocol ESH-IP 2010 from the European Society of Hypertension.
- The radio interference emitted by this product is within the limits specified in CISPR11/EN 55011, class B.
- The CE marking covers only the accessories listed in the "Order Information" chapter.
- 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.**
- The symbol  means: Follow the instructions given in the operator’s manual. It indicates points, which are important to avoid faulty measurements or injuries like strangulation of the arm.
- 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.
- On request, PAR Medizintechnik will provide a Service Manual.
- The safety information given in this manual is classified as follows:

Danger

Indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning

Indicates a hazard. If not avoided, the hazard can result in death or serious injury.

Caution

Indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

- To ensure patient safety and interference-free operation and to guarantee the specified measuring accuracy, we recommend using only original accessories available through GE Healthcare. The user is responsible for application of accessories from other manufacturers.
- Any serious incident occurring in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

PAR Medizintechnik GmbH & Co. KG
Rigistr. 11
12277 Berlin
Germany
Tel. +49 30 235 07 00

The country of manufacture is indicated on the device label.

1 Application, Safety Information

1.1 Application

Intended Use

The PHYSIO-PORT UP device is intended to be used in combination with a suitable blood pressure cuff for the automatic non-invasive measurement of the blood pressure (single or 24-h-measurement of the systolic, diastolic and mean value), the heart rate and other vital or non-vital sign parameters of human beings in the clinical daily routine.

Indications

If the blood pressure cuffs listed in chapter "Order Information" on page 28 fit the patient, it can be used on adults and pregnant (including pre-eclamptic) women.

PHYSIO-PORT UP is **not** suitable for blood pressure measurements in neonates. Also, it is **not** suitable for use in intensive-care medicine. PHYSIO-PORT UP is intended for use following consultation and instruction by a physician.

PHYSIO-PORT UP can record up to **400** blood pressure measurements at selectable intervals and save the results.

Note

The software PhysioPortWin supports up to 400 memory readings.

There is a choice of three different measurement protocols.

Using PHYSIO-PORT UP with PhysioPortWin

PHYSIO-PORT UP can be operated in conjunction with PhysioPortWin. If the USB port is used, it is necessary to install the appropriate driver first (see "Software Installation" on page 23). With these systems, individual measurement protocols can be created and the stored data can be reviewed on screen in tabular and graphic form. The patient ID used by the analysis program can be stored in PHYSIO-PORT UP to allow the collected data to be downloaded without selecting the patient first (refer to the respective Operator Manuals; you will find the PhysioPortWin manual on the USB-Stick).

Biocompatibility

The parts of the equipment described in this manual, including all accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards if used as intended. If you have questions in this matter, please contact PAR Medizintechnik.

The 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 deter- mined 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 com- mon 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. (see Fig. 1-1).

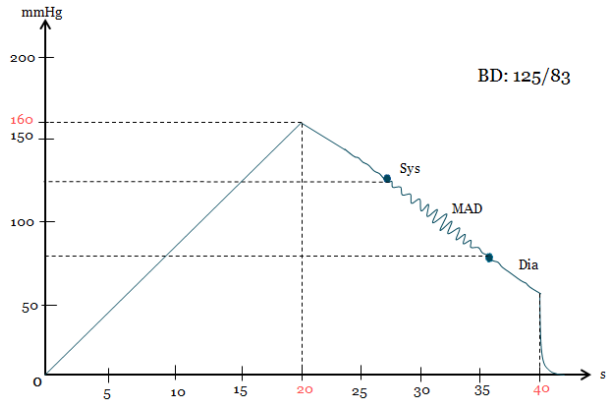


Fig. 1-1 Waveform representing the pressure in the cuff during a measurement using the deflation measurement method: systolic pressure at 125 mmHg, diastolic pressure at 83 mmHg

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. The measurement typically takes only approx. 20 seconds. (see Fig. 1-2)

If disturbances occur during measurements with the inflation measurement method, which may be due to motion artifacts, for example, PHYSIO-PORT UP will automatically switch to the deflation measurement method and complete the blood pressure measurement.

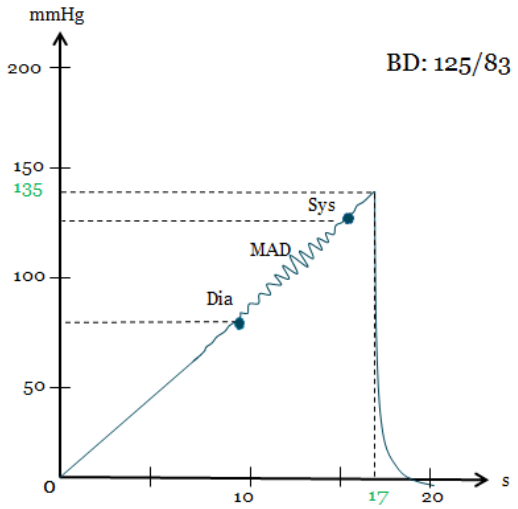


Fig. 1-2 Waveform representing the pressure in the cuff during a measurement using the inflation measurement method: systolic pressure at 125 mmHg, diastolic pressure at 83 mmHg

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. (Each 10 cm difference result in a pressure deviation of 8.0 mmHg.)

When the patient is sitting, lying, or standing during measurements the cuff is automatically at the correct level.

1.2 Functional Description

The PHYSIO-PORT UP monitor accommodates the blood pressure measuring system and a microprocessor for system control and data processing.

A second microprocessor with a second pressure transducer and a second valve are provided for control of the technical safety.

The monitor is powered by two AA size batteries (either rechargeable NiMH batteries or alkaline batteries).

1.3 Safety Information

Danger

Risk to Persons —

– ***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 (N_2O), skin cleansing agents, or disinfectants.***

Warning

Risk to Persons —

– ***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. To ensure such a secure connection the equipment or parts of systems have to comply with the standard IEC 60601-1 or IEC 60950-1.***

– ***Connection of this device to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks.***

– ***Changes to the IT-network could introduce new risks that require additional analysis. Changes to the IT-network include:***
  - ***changes in network configuration***
  - ***connection of additional items (e.g. connecting another PHYSIO-PORT UP device to another port of the PC can lead to interference during data transfer)***
  - ***disconnection of items***
  - ***update or upgrade of equipment***

– ***PHYSIO-PORT UP may be connected to a PC with the PhysioPortWin software. While connected to any of these devices, PHYSIO-PORT UP must be disconnected from the patient.***

– ***Chemicals required, for example, for the maintenance of the equipment must under all circumstances be prepared, stored, and kept at hand in their specific containers. Failure to observe this instruction may have severe consequences.***

– ***The equipment has no protection against the ingress of liquids. Liquids must not enter the equipment. Equipment into which liquids have entered must be inspected by a service technician before use.***

Warning

Risk to Persons —

- ***Before cleaning, PHYSIO-PORT UP must be disconnected from other equipment (f. e. PC).***
- ***Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach.***

Incorrect measurements —

- ***Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that external equipment operated in the vicinity of PHYSIO-PORT UP complies with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems etc. are possible sources of interference as they may emit higher levels of electromagnetic radiation.***

Caution

Equipment damage, risk to persons—

- ***Before connecting the battery charger to the power line, check that the voltage ratings on the nameplate match those of your local power line.***
- ***The battery charger is not a medical device. Its use in the patient environment is not permitted.***
- ***Before using the equipment, the operator must ascertain that it is in correct working order and operating condition.***
- ***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 the manufacturer or your local, authorized dealer (http://www.par-berlin.com).***

2 Controls and Indicators

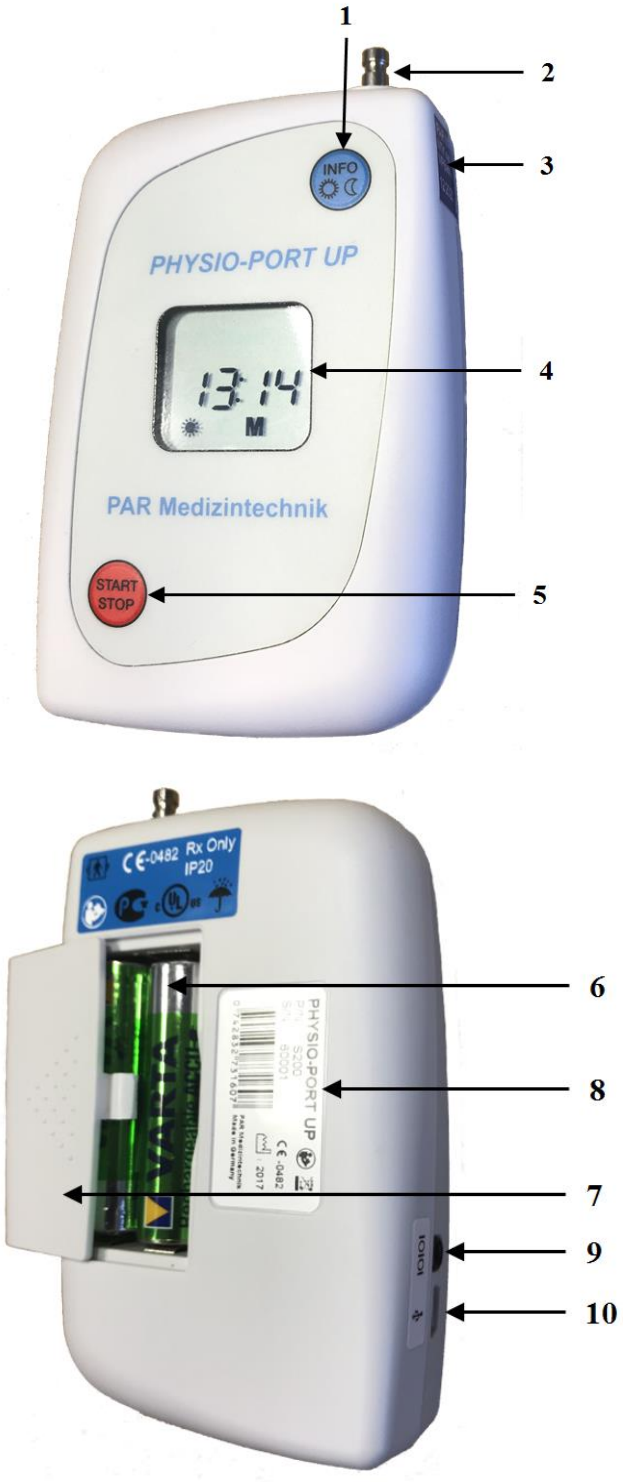


Fig. 2-1 Controls and indicators of PHYSIO-PORT UP

Functions of Button INFO

Button INFO	Message on display	Function
Push once	H 1	clear memory
Push twice	H 2	set date and time
Push 3 times	H 3	select measurement protocol
Push 4 times	H 4	activate calibration mode
Push 5 times	H 5	display firmware version
Push 6 times	H 6	select energy source
Push 7 times	H 7	enable/disable audio signal
Push 8 times	H 8	toggle pressure unit between mmHg and kPa
Push 9 times	H 9	select measurement method: deflation measurement method or inflation measurement method

1 *Button INFO: push to display the most recent parameter readings. The display will show:*
- systolic value "S" (unit mmHg or kPa shown on the display)
- diastolic value "D" (unit mmHg or kPa shown on the display)
- pulse rate "HR" (unit min^{-1})
The same button is used
- to toggle between the day phase and the night phase (section "Toggling Between Day and Night Phase") and
- to program the BP monitor (chapter 3 "Setup")

2 *Connection for blood pressure cuff*

3 *Calibration mark*

4 *Liquid crystal display (LCD)*

5 *Button START STOP: push to start and stop a measurement and to confirm entries*

6 *(Rechargeable) batteries*

7 *Lid covering battery compartment*

8 *Nameplate (example)*

9 *Port for connection to PC (RS232)*

10 *Port for connection to PC (USB)*

Explanation of Signs and Symbols

Symbols used on the equipment and on the packaging

Follow the instructions given in the operator's manual.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed an unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning if your equipment.

Type BF applied part (defibrillation-proof, recovery time t_R < 1s)

Article number (Manufacturer)

Serial number

Quantity

Medical device

CE marked per the Regulation (EU) 2017/745 of the European Union.
Notified body: MEDCERT GmbH

Protection against ingress of solid foreign objects and no protection against ingress of water.

No protection against contact and ingress of objects and protection against dripping water when tilted at 15°.

Keep dry

Temperature limits

Humidity limits

Air pressure limits

USB port, connection to PC

Serial port, connection to PC

Manufacturer's identification

Date of manufacture.
The number found under this symbol is the date of manufacture in the YYYY-MM format.

Ambulant Blood Pressure Measurement Device

PC System Ambulant Blood Pressure Measurement Device

Calibration mark, in Germany mandatory (see "Technical Inspection of the Measuring System")

Symbols used on the display

Blinks with each detected oscillation; is continuously displayed when the monitor contains data.

Blinks when the batteries are almost depleted; is continuously displayed when batteries are discharged and no more BP measurement can be taken.

Day phase selected

Night phase selected

Further relevant symbols used on the battery charger

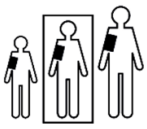
Protection class II equipment

For indoor use only

UL marking

Symbols used on the blood pressure cuff

Follow the instructions given in the operator manual.



Blood pressure cuff is suitable for adults of the framed size (Medium-sized, Small, Large, Extra-Large)

Lot number

UDI-DI number

Blood pressure cuff is suitable for the indicated arm circumference

When applying the cuff, this arrow has to lie on the brachial artery.

The end of the cuff must be situated within this range when the cuff is closed.

This line identifies the end of the cuff which must be situated within the range identified by the INDEX label when the cuff is closed.

Latex-free blood pressure cuff.

CE marking, blood pressure cuff complies with (EU) 2017/745.

3 Setup

Basic Facts about the sBattery Supply

PHYSIO-PORT UP is either powered by two rechargeable nickel-metal hydride batteries (NiMH) or by two alkaline batteries. The device must be set to the power source used (see section "Inserting Batteries"). The device also contains a Lithium cell that powers the clock. The Lithium cell can only be replaced by a service technician.

The capacity of two fully charged or new batteries is sufficient for up to 48 h of operation or 400 blood pressure measurements.

The capacity of rechargeable batteries decreases with age. If the capacity of fully charged batteries is considerably less than 24 hours, the batteries must be replaced.

Caution

Equipment Damage —

- ***Only use the original rechargeable, size AA nickel-metal hydride batteries (from manufacturers such as Sanyo, Panasonic, Energizer, Duracell, Varta, GP) with a capacity ≥ 1500 mAh or high-rate discharge, size AA alkaline batteries (such as Panasonic Evoia, Energizer Ultimate, Duracell Ultra, Duracell Power Pix, Varta maxtech).***
- ***Charge the NiMH batteries to capacity before using them for the first time.***
- ***Recharge the NiMH batteries immediately after use and do not leave batteries uncharged.***
- ***Use only the original charger to recharge the NiMH batteries.***
- ***Do not attempt to recharge alkaline batteries.***
- ***If PHYSIO-PORT UP will not be used for one month or more, remove the (rechargeable) batteries from the device.***
- ***Batteries must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the batteries.***

Inserting Batteries

- Open the battery compartment on the back of PHYSIO-PORT UP as shown in Fig. 3-1.

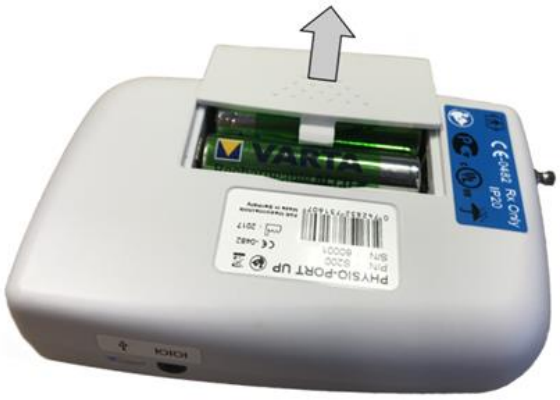


Fig. 3-1 Opening the battery compartment

- Place the two batteries in the compartment as indicated by the symbols.

Selecting the Energy Source

- Turn on the BP monitor as follows:
  either by inserting the batteries or by briefly pressing the START STOP button.
- Wait for the time to be displayed.
- Push INFO six times: The display shows "H 6".
- Push START STOP: the display shows "AAAA" when the BP monitor is set up for rechargeable NiMH batteries (as shipped) and "bbbb" when it is set up for alkaline batteries.
- Confirm the displayed information with START STOP or change the selection with INFO and confirm the new selection with START STOP.
- Next, the BP monitor will briefly display the capacity of the inserted batteries. "A 100", for instance, means that the rechargeable batteries have a capacity of 100%, i.e., they are fully charged, "b 50" means that the alkaline batteries have a capacity of only 50%, i.e., they are half depleted
- Place the lid on the battery compartment and close.

Note

The energy source needs to be selected only when the BP monitor is put into service for the first time or when you change from NiMH to alkaline batteries and vice versa.

Charging NiMH Batteries

Caution

Equipment damage, patient hazard —

- ***The battery charger is not a medical device. Its use in the patient environment is not permitted.***
- ***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 contact 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.***
- ***After quick charging, please wait for some minutes before another quick charge. Otherwise, the temperature sensors will not function correctly.***

If PHYSIO-PORT UP 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.

Fig. 3-2 Charging unit and power supply and USB cable

Fig 3-3 European plug for the battery charger, international plugs are available on request.

- 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 two or four rechargeable batteries into the charging unit, observing the correct polarity.

Charging Batteries with the Charging Unit

To charge the NiMH batteries that are part of the PC-system, follow the instructions given in the accompanying manual for the battery charger.

Switching PHYSIO-PORT UP ON and OFF

The PHYSIO-PORT UP monitor has no power switch.

Switch the device on and off as follows:

To switch ON: Insert charged batteries OR briefly press START STOP.

To switch OFF: Remove the batteries or press START STOP for 3 seconds.

Performance Check

When turned on, PHYSIO-PORT UP runs a self-test that includes all symbols and segments on the LCD (Fig. 3-4). Then it checks the batteries and indicates the remaining capacity. "A 100", for instance, means that the rechargeable batteries have a capacity of 100%, i.e., they are fully charged. "b 50" means that the alkaline batteries have a capacity of only 50%, i.e., they are half depleted.

The minimum battery capacity for a 24-hour measurement is 90%.

If the capacity is below 90%, new or fully charged batteries must be inserted.

BP monitors that have passed the self-test and completed the battery test will indicate the following information:

– the time of day,
– the measuring phase (day ☀ / night ☾), and
– whether data are stored in the BP monitor (**M**) (see Fig. 3-5).

The BP monitor will also emit an audio signal if enabled.

Fig. 3-4 Test display on LCD

*Fig. 3-5 Example: display after successful self-test (**M** = BP data in memory, ☀ measuring phase: day)*

Before using PHYSIO-PORT UP on a patient

1. clear the memory
2. check date and time and adjust if required
3. select a measurement protocol
4. enable or disable the audio signal.

Note

When using PHYSIO-PORT UP in conjunction with PhysioPortWin, it is recommended to perform the first three steps at the PC.

Clearing the Memory

The symbol **M** on the display indicates that the memory holds BP data. If these data still need to be analyzed, refer to chapter 5 "Data Output" for details on data evaluation. If you do not need the data any more, delete it as follows:

- Briefly switch PHYSIO-PORT UP off and on again and wait for the time to be displayed.
- Push INFO: the display indicates "H 1".
- Push START STOP: the display indicates "LLLL"
- To delete the data, push START STOP again: the display indicates "0000", followed by the time (if you do not wish to clear the memory, turn off the BP monitor instead of pushing START STOP).

Selecting the Measurement Method

- Briefly switch PHYSIO-PORT UP off and on again and wait for the time to be displayed.
- Push INFO 9 times: the display indicates "H 9".
- Push START STOP: the display indicates "0000" if the selected method is the deflation measurement method, or "1111" if the selected method is the inflation measurement method.
- Either confirm with START STOP or switch to the other option with INFO, then confirm with START STOP.

Time and Date

Usually the BP monitors are set to the correct time and date before delivery. Therefore, the time only needs to be corrected to change between Standard Time and Daylight Saving Time.

Setting Time and Date

- Briefly switch PHYSIO-PORT UP off and on again and wait for the time to be displayed.
- Push INFO twice: the display indicates "H 2".
- Push START STOP: The year will be displayed, e.g. "2020".
- If the indicated year is correct, confirm it with START STOP or correct it with INFO, then confirm with START STOP
- The month will be displayed, e.g. "03".
- If the indicated month is correct, confirm it with START STOP or correct it with INFO, then confirm with START STOP.
- In the same manner, correct day, hour, and minute.
- In the end, the time of day will be displayed again.

Selecting the Pressure Unit

- Briefly switch PHYSIO-PORT UP off and on again and wait for the time to be displayed.
- Push INFO 8 times: the display indicates "H 8".
- Push START STOP: the display indicates "mmHg" or "kPa".
- Either confirm with START STOP or switch to the other option with INFO, then confirm with START STOP.

Measurement Protocols

There is a choice of three different measurement protocols:

Protocol	**Day Phase** (7 a.m. to 10 p.m.)	**Night Phase** (10 p.m. to 7 a.m.)
P 1	every 15 minute	every 30 minute
P 2	every 20 minute	every 40 minute
P 3	every 30 minute	every 60 minute

Max. inflation pressure: day phase 250 mmHg
night phase 220 mmHg

Selecting a Measurement Protocol

- Briefly switch PHYSIO-PORT UP off and on again and wait for the time to be displayed.
- Push INFO 3 times: the display indicates "H 3".
- Push START STOP: the display indicates "LLLL" (Selecting a protocol automatically clears the memory. If you want to retain the data, switch the BP monitor off.)
- Push START STOP: the display indicates "P1" (protocol 1).
- Either select program 2 or 3 by pushing INFO or
- Confirm the selected protocol with START STOP.

Enabling or Disabling the Audio Signal

- Briefly switch PHYSIO-PORT UP off and on again and wait for the time to be displayed
- Push INFO 7 times: the display indicates "H 7".
- Push START STOP: the display indicates "0000" when the audio signal is disabled, and "1111" when it is enabled.
- Either confirm with START STOP or switch to the other option with INFO, then confirm with START STOP.

4 Application

Applying the Cuff

Warning

Risk to Persons —
Disconnect PHYSIO-PORT UP from other equipment (f. e. PC) before connecting it to the patient.

- Select the appropriate cuff size (see cuff label). **When the cuff is too small the BP values will be overrated, when it is too big, the measured values will be too low.**

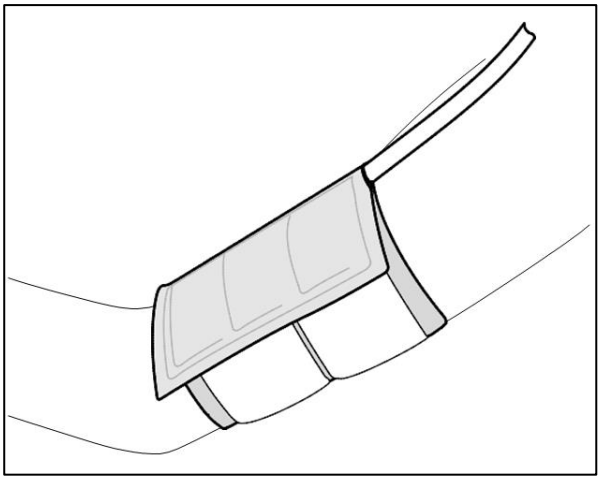


Fig. 4-1 Applying the cuff

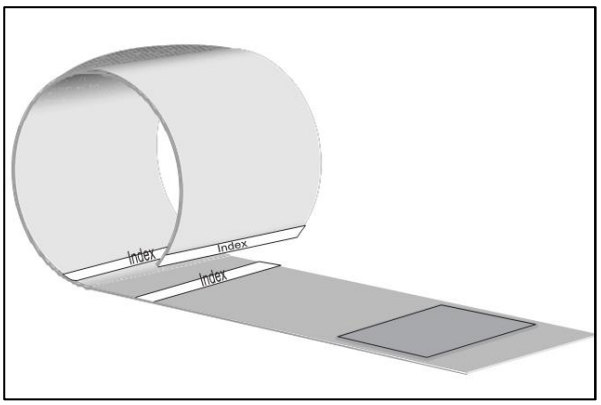


Fig. 4-2 Applying the cuff

Warning

Risk to Persons —

- ***The effect of blood flow interference can result in a harmful injury to the patient caused by continuous cuff pressure due to connection tubing kinking.***
- ***Too frequent measurements can cause injury to the patient due to blood flow interference.***
- ***The application of the cuff over a wound can cause further injury.***
- ***The application of the cuff and its pressurization on the arm on the side of a mastectomy is not recommended.***
- ***The pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.***
- ***By watching the limb, it is necessary to check that operation of the PHYSIO-PORT UP does not result in prolonged impairment of patient blood circulation.***

Caution

Incorrect measurements —

- ***Use only the cuffs listed in chapter „Order Information“.***
- ***Replace cuffs on a regular basis. Damaged Velcro fasteners may cause incorrect readings.***
- ***When using a small cuff, only the deflation measurement method should be used (see chapter "General Information on Ambulatory BP Measurement").***

- Always insert 2 fully charged NiMH batteries or two new alkaline batteries, before starting a measurement.
- Check that the memory has been cleared (see "Clearing the Memory").

- Place the cuff on that arm of the patient which is used less frequently during normal daily activities: on adults about 2 fingers' breadth above the bend of the elbow. Bending the arm must not change the cuff level.
- It is recommended to place a hose made of mull between arm and cuff.

Verify that

- the cuff tubing points up toward the shoulder (Fig. 4-1)
- no compression or restriction of connection tubing can occur
- the side with the Patient label is on the skin (single-use cuffs)
- the arrow is located above the brachial or femoral artery
- the dashed white line at the end of the cuff is located between the two Index lines when you close the cuff (if this is not the case, select another cuff size, see Fig. 4-2),
- the cuff fits snugly around the arm but does not compress the blood vessels
- the cuff and the PHYSIO-PORT UP are used inside the ambient conditions for operation and inside the measuring range (s. chapter „Technical Specifications“

Performing a Trial Measurement

- Turn on PHYSIO-PORT UP and place it in the wearable pouch. There is an aperture in the pouch to accommodate the cuff connection tube.
- Attach the pouch to the patient (shoulder strap, belt). For reasons of hygiene, it is not advised to carry the pouch on the bare skin.
- Guide the pressure tubing around the patient’s neck as a strain relief and connect it to the blood pressure cuff port of PHYSIO-PORT UP (**2**, Fig. 2-1). Do not wrap the pressure tubing completely around the neck to avoid strangulation of the patient. You must hear the connector click into place. Ensure that the tube is not kinked or blocked during the measurement.
- Check that the display indicates the time of day. (If the memory contains data from a previous procedure, the letter "M" will appear on the display when you turn on the device. If you still try to initiate a measurement, the message "LLLL" prompts you to clear the memory. Push twice to delete the data. If you want to retain the data, turn off the device instead of pushing .)
- **To avoid erroneous measurements, ensure that the patient does not move during the trial measurement. The patient may stand or sit.**
- Push START STOP to initiate the first measurement.

Within a few seconds, the device starts inflating the cuff. When the inflation pressure has been reached, the cuff will gradually be deflated (deflation measurement method) or the pressure will be released quickly (inflation measurement method). The changing cuff pressure is indicated on the display and the letter "M" appears with each detected oscillation. At the end of the measurement, the measured data will be displayed

- the systolic readings (S in mmHg or kPa)
- the diastolic readings (D in mmHg or kPa) and
- the pulse rate (HR/min^{-1}).

If an error code, such as "E 29" (insufficient number of oscillations detected) is displayed after the measurement, tighten the cuff a little and push START STOP again (see also chapter „Error Codes).

If the trial measurement has been completed successfully, the device is ready for automatic measurements.

Patient Information

Advise your patient

- **not to move while a measurement is being taken to avoid motion artifacts that may lead to erroneous readings and to keep the cuff inflation time as short as possible**
- to place the PHYSIO-PORT UP with the wearable pouch on the night stand while in bed,
- how to switch the device manually from the day to the night phase (see chapter „Toggling Between Day and Night Phase“),
- to note down special circumstances such as driving in a car or using public transport, which may cause erroneous measurements due to vibrations, or situations of emotional stress; this information will help you as a doctor to interpret the measurements in context
- that measurements can be initiated in these situations by pressing START STOP,
- that the measurement can be stopped at any time with START STOP (the cuff will be deflated),
- not to open the battery compartment or the device,
- about the audio signal an its meaning,
- to protect the device against water, excessive humidity and excessive temperatures,
- not to remove the device from the wearable pouch,
- to remove the pressure hose only in emergency situations (see warning below),
- that the cleaning may only be carried out by qualified medical personnel and not by the patient.

Warning

Risk to Persons —

Instruct your patient

- ***to terminate the measurement with START STOP, whenever the cuff is not deflated within about 2 minutes,***
- ***to remove the cuff if it is not deflated after activation of the START STOP button. This could be due to kinked tubing. The cuff must be reapplied as described earlier before additional measurements can be taken.***

Note

The operator’s manual is restricted to professional healthcare personnel. Do not deliver this document to the patient. Please give the patient a copy of the patient instruction (see page 36).

Absolute Contraindications:

The application of the cuff is prohibited on an arm with

- dialysis shunt
- fresh operation wounds
- mastectomy

Relative Contraindications:

If the doctor ascertains a positive benefit-risk ratio, the application of the cuff is allowed on the arm with:

- lymphedema
- paresis or plegia
- arterial or venous vascular access

Other diagnostic or therapeutic measures do not negatively affect the blood pressure measurement.

Note

Professional healthcare personnel have to give some information about the accuracy of the PHYSIO-PORT UP to the patient.

General Information on Ambulatory BP Measurement

These are the buttons on PHYSIO-PORT UP used during an ambulatory blood pressure measurement:

starts and stops a measurement

displays the most recent measurement results or the most recent error message, toggles between day and night phase (see next section)

Deflation Measurement Method:

For the first measurement, the cuff is inflated to a pressure of 160 mmHg (initial pressure). For subsequent measurements, the device inflates the cuff to a pressure which is 15 mmHg above the systolic value of the previous measurement (minimum inflation pressure: 120 mmHg). If the measured value is above the inflation pressure, the device will increase the cuff pressure another 50 mmHg.

Inflation Measurement Method:

For each measurement, the device inflates the cuff to a pressure just above the expected systolic pressure.

A manual measurement can be taken at any time between the automatic measurements. Manual measurements are marked in the tabular BP data in the software PhysioPortWin.

If unsuccessful, the device will repeat a measurement after 2 minutes. An error code referring to failed measurements is generated in PhysioPortWin only after three consecutive unsuccessful measurements.

Error codes E02 (battery depleted), E06 (inflation time over) and E08 (maximum number of pressure measurements taken – 200 or 400) do not lead to a second measurement. The next measurement after error code E06 occurs at the selected interval.

After error codes E02 and E08, the device enters the power-save mode to prevent over-discharging of the rechargeable batteries. This mode can only be terminated by turning the device off and on again.

Toggling Between Day and Night Phase

In the three measurement protocols, the day phase lasts from 7 a.m. to 10 p.m. and the night phase from 10 p.m. to 7 a.m. On the display, the two phases are represented by the symbols ☀ (day) or ☾ (night).

Patients whose day and night phases are different from these predefined periods can push the 

button twice to change from one phase to the other.

Note

If the measurement protocol was created with PhysioPortWin and only one BP period has been specified, switching from one phase to the other will leave the measurement intervals unchanged. They will always be the same. The information "day phase" and "night phase" is only used to identify the measurements.

Audio Signal

If enabled (see page 18), the audio signal will be emitted in the following situations:

- shortly after PHYSIO-PORT UP was switched on
- just before PHYSIO-PORT UP starts inflating the cuff (during the day phase only)
- after PHYSIO-PORT UP has detected an erroneous measurement

5 Data Output

The measurement data are output via PhysioPortWin.

Warning

Risk to Persons—
Disconnect PHYSIO-PORT UP from other equipment (f. e. PC) before connecting it to the patient.

Note

If the USB port is used (PhysioPortWin only), it is necessary to first install the appropriate driver (see "Software Installation").

- Put the PC-based system into operation (see Operator Manual of PhysioPortWin).
- Turn off PHYSIO-PORT UP.
- Connect PHYSIO-PORT UP to the PC system:
  – via cable 2001589-040 if the USB port of PHYSIO-PORT UP is used (b, Fig. 5-1)
  – via cable 2001589-011 if the serial port of PHYSIO-PORT UP is used (a, Fig. 5-1)
- Turn on PHYSIO-PORT UP and wait for the time to be displayed.

For more information about data output, please refer to the Operator's Manual of PhysioPortWin.

When you have finished downloading data to PhysioPortWin and do not intend to continue working with this system, disconnect PHYSIO-PORT UP and turn it off.

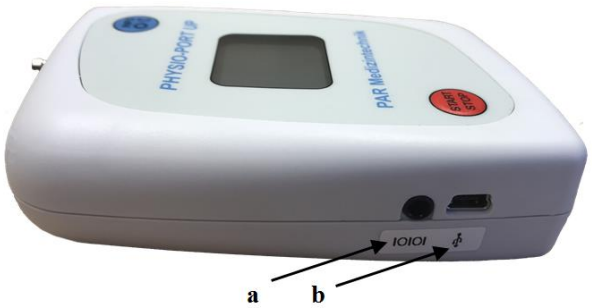


Fig. 5-1 Connections for PC cable
a RS232 port
b USB port

6 Error Codes

E 02 Batteries depleted. Code appears when the battery capacity is insufficient for new BP measurements. The device differentiates between two states: the memory has just been cleared (i.e., the battery test is performed with a higher drain to ensure that fresh batteries will be inserted at the beginning of the measurement) or measurements have already been taken.

E 03 Measurement time over. Code is displayed after measurement duration of 180 seconds.

E 06 Inflation time over. The maximum inflation time of 130 seconds has elapsed. This condition indicates a leak in the cuff or tubing, or a defect at the cuff connector

E 07 This code appears

- when the device could not determine a systolic value although the cuff pressure was already increased twice
- when the current cuff pressure would exceed the selected maximum pressure.

E 08 400 pressure measurements taken; storage capacity exhausted.

E 14 Diastolic reading below 40 mmHg. Code appears when the cuff pressure has dropped to 40 mmHg and no diastolic pressure could be identified (PHYSIO-PORT UP does not measure diastolic pressures below 40 mmHg).

E 15 Motion artifact during diastole detection.

E 17 Internal hardware error. Please contact your local authorized dealer (http://www.par-berlin.com).

E18 Systolic reading outside measuring range.

E 19 Diastolic reading outside measuring range. (Codes **E 18** and **E 19** are displayed when the systolic and diastolic values are outside the range in which oscillations were detected.)

E 21 Difference between systolic and diastolic pressure too small (10 mmHg or less).

E 22 Motion artifact during systole detection.

E 26 Systolic reading below measuring range.

E 27 Systolic reading above measuring range.

E 29 Insufficient number of oscillations detected: For a correct measurement, the system must detect a minimum of 8 oscillations.

For **deflation measurement method**:

Tighten the cuff so that one finger, but not two, can be inserted between the patient's arm and the cuff. At the same time the device switches to a deflation rate of 4 mmHg/s. When it detects more than 13 oscillations later on, the rate changes to 6 mmHg/s.

For **inflation measurement method**:

This error message will not be displayed because PHYSIO-PORT UP automatically switches to the deflation measurement method if the number of detected oscillations is insufficient.

7 Software Installation

Install PhysioPortWin and the USB driver on your PC only if you are familiar with the Windows operating system.

PhysioPortWin and the USB driver run only under these operating systems: Windows 10, Windows 8.1 Pro and Enterprise 64-bit, as well as Windows 7 Professional, respectively as 32-bit and 64-bit-version.

7.1 PhysioPortWin

To install the PhysioPortWin software on PC, insert the USB stick into a free USB port of your PC. The installation is then started as follows:

- Open the Windows Explorer.
- Select the USB stick drive.
- Double click on setup.exe and follow the instructions.

The installation of the software PhysioPortWin is described in more detail in the User Manual PhysioPortWin.

7.2 System requirements

- Processor: min. 1.6 GHz Dual Core
- Memory: min. 2 GB
- Hard drive capacity: min. 250 GB
- Screen resolution: min. 1024 × 768 pixel
- Connectors: USB (1.1, 2.0, or 3.0)

Note

If you will be using the serial port of PHYSIO-PORT UP (a, Fig. 5-1), the installation is now complete.

To be able to use the USB port of PHYSIO-PORT UP (b, Fig. 5-1), you need to install the USB driver and check the communication as described below.

7.3 USB Driver

You will need administrator privileges for installation.

1. Turn on the PC and the monitor. Exit ALL programs.

2. Insert the storage device (USB stick) with the USB driver. If the driver setup does not start up automatically, start "setup.exe" (on the storage device in folder "Disk1") via Windows Explorer

3. Follow the displayed prompts.
   Select *Allow*, if the system informs you that you are using an unidentified program.

4. Click *Finish* to complete the first part of the USB driver installation procedure.

5. Turn on PHYSIO-PORT UP and connect it to the PC, using the USB connection cable. Windows will automatically detect PHYSIO-PORT UP (TUSB3410 device).

6. Follow any additional prompts that may be displayed.

7. When Windows indicates that the drivers were successfully installed and the new hardware can be used, remove the USB driver storage device from the PC.

7.4 Checking the Port

USB port check only:
For a check of the USB port, turn on the PHYSIO-PORT UP device and connect its USB port to the PC.

1. Start the Device Manager of the operating system.
2. Double-click *Ports (COM and LPT)* to view all ports.

If PhysioPortWin is used or if a USB serial port/TUSB3410 Device between COM1 and COM4 has been selected, it is not necessary to choose another port. Note down the selection because the same port must be set in PhysioPortWin, and close all windows to return to the Windows desktop.

If a USB serial port greater than COM4 has been selected, one of the ports COM1 through COM4 must be disabled at the PC so that it can be assigned to the USB port.

3. Select one of the ports COM1 through COM4 that is not needed for other devices and disable it (right-click > Disable). Confirm the message that the device will not be functional any longer.
4. When using the **USB port**:

   Right-click *USB - Serial Port* (COM X) and click *Properties.*

5. Click *Port Settings > Advanced*, and at *COM Port Number*, select the port that you disabled ear-lier. Select *Yes* if a message appears that this COM port is already used by another device. The selected port must be also be set in PhysioPortWin.

6. Select *OK* where needed and/or close all windows to save the settings.

Disconnect the USB cable and restart Windows.

8 Cleaning, Maintenance, Disposal

8.1 Cleaning and Disinfection of the Equipment Surface

Warning

Shock Hazard —
Disconnect PHYSIO-PORT UP from the PC or printer before cleaning.

- Turn off PHYSIO-PORT UP.
- Wipe the device and the associated wearable pouch with waist belt down with a soft, lint-free cloth for cleaning. Liquids must not penetrate the device. Spray disinfection has proved successful. Incidin® Foam or equivalent disinfectants that are used in practices or hospitals are suitable (Please respect the information of the manufacturer especially regarding the exposure time).

Caution

Equipment Damage —
Do not disinfect the device surface with phenol-based disinfectants or peroxide compounds.

Warning

Shock Hazard, Equipment Damage —
Equipment into which liquids have entered must be inspected by a service technician before use.

Warning

Risk to Persons —
Equipment and accessory have to be disinfected between the uses on different patients. Additionally national regulations for the cleaning and disinfection have to be considered.

8.2 Cleaning and Disinfection of the Cuffs

- Use a moist cloth to wipe the cuffs clean if they are only slightly soiled.
- Clean cuffs that are heavily contaminated by washing them with soapy water or a suitable cleaning agent that contains a disinfectant (do not machine-wash). Ensure that no liquid penetrates into the cuff bladder or the pressure tubing.
- The cuffs can be disinfected with isopropyl alcohol 70%, ethanol 70%, mikrozid universal liquid, buraton rapid, Sporicidin, or Cidex. After disinfection, rinse the cuff thoroughly with tap water and air-dry.
- Moreover, spray disinfection has proved successful after the usage of the cuff. Incidin® Foam or equivalent disinfectants that are used in practices or hospitals are suitable (Please respect the information of the manufacturer especially regarding the exposure time).
- After the cleaning, you have to rinse the cuff thoroughly with clear water and let it air-dry at room temperature for about 15 hours.

8.3 Cables

- Disconnect cables from the device before cleaning.
- Use a cloth moistened with soapy water to wipe the cables clean. Do not immerse cables in liquid.

8.4 Maintenance

Checks before each use

Before each use, visually check the device and the cables for signs of mechanical damage.

If you detect damage or impaired functions which may result in a hazard to the patient, the operator or third persons, the device must be repaired before it can be used again.

Technical Safety Inspections

For safety, the device requires regular maintenance. To ensure functional and operational safety of PHYSIO-PORT UP, Technical Safety Inspections should be carried out at least every 2 years.

Caution

These checks shall be carried out by PAR Medizintechnik or authorized companies.

The checks can be carried out within the framework of a service agreement; please contact PAR Medizintechnik Service for details. The device does not require any other maintenance.

Technical Inspections of the Measuring System

The non-invasive pressure measurement system of PHYSIO-PORT UP should be inspected every two years.

Caution

These checks shall be carried out by PAR Medizintechnik or by authorized companies.

The checks are carried out within the framework of a service agreement; please contact PAR Medizintechnik Service for details.

8.5 Disposal of the Product

The products described in this operator manual must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
The cuffs can be disposed as contaminated hospital waste.

Calibration Mode

(e.g., to check the pneumatic system for leaks)

- Connect a rubber bulb between pressure tubing and cuff, using a T-adapter.
- Roll up cuff tight.
- Turn device off and on again after a few seconds, then wait for time to be displayed.
- Push INFO four times: the display indicates "H 4".
- Push START STOP: the display indicates an internal value that must be between 25 and 100. If the displayed value is outside this range, PHYSIO-PORT UP must be returned for repair.
- Push START STOP again: the display indicates "0" (the display now indicates the pressure in mmHg).
- Generate a test pressure of 200 mmHg and measure the pressure decrease after waiting at least 30 seconds. (Pressure decreases between 3 mmHg and 5 mmHg are typical; a pressure decrease > 6 mmHg indicates a leak and the system needs to be repaired.)
- Push START STOP to exit the calibration mode.

Viewing the Firmware Version

- Turn on the device and wait for the time to be displayed.
- Push INFO five times: the display indicates "H 5".
- Push START STOP: the firmware version is indicated, e.g.,
  - "30" = firmware version 3.0
- Push START STOP to end the display.

9 Technical Specifications

Measuring Range

- systolic pressure 60 to 260 mmHg (8.0 to 34.6 kPa)
- diastolic pressure 40 to 220 mmHg (5.3 to 29.3 kPa)
- mean pressure 45 to 250 mmHg (6.7 to 33.3 kPa)
- pulse rate (HR) 35 to 240 min^{-1}

Measurement Accuracy (determined in a clinical study according to ISO 81060-2)

- deflation measurement method:
  Systole: 0.7 ± 2.5 mmHg
  Diastole: 0.5 ± 2.2 mmHg
  Puls rate (HR): 1.0 ± 2.6 min^{-1}
- systematic measurement deviation for inflation measurement method:
  Systole: 0.9 ± 3.8 mmHg
  Diastole: 0.6 ± 3.2 mmHg
  Pulse rate (HR): 0.6 ± 3.5 min^{-1}

Measurement Capacity

- up to 400 blood pressure measurements

Interfaces

- USB (1.1 or 2.0)
- RS-232 (9.600 Bd / 8N1)

Battery

- 2 AA size rechargeable NiMH batteries, 1.2 V, > 1.500 mAh or
- 2 AA size alkaline batteries

Battery Charge Time

- 2 to 3 hours

Maximum cuff pressure

- 300 mmHg

Measuring Method

- Oscillometric, selectable measurement method: deflation measurement method or inflation measurement method

Battery Charger

- protection class II, IP20
- 100 to 240 VAC 50/60 Hz, 0.5 A

Ambient Conditions

Operation

- temperature + 0 °C…+ 55 °C
- relative humidity 15 % and 93 %, no condensation
- atmospheric pressure between 700 hPa and 1060 hPa
- altitude (relative to sea level) -400m to 2800 m

Note

The device needs 30 min to get ready for its intended use and reach the operation conditions form the minimum storage temperature and the maximum storage temperature, if the room temperature is 20 °C.

Transport and Storage

- temperature -25 °C and +70 °C
- relative humidity between 10 % and 93 %, no condensation
- atmospheric pressure between 500 hPa and 1060 hPa
- altitude (relative to sea level) -400 m to 4500 m

Dimensions

- height: 27 mm
- width: 73 mm
- depth: 108 mm
- weight: < 210 g, incl. Batteries

Protection Class

- IP20: PHYSIO-PORT UP
- IP02: wearable pouch of the PHYSIO-PORT UP
- IP22: PHYSIO-PORT UP in wearable pouch

Expected Service Life

- PHYSIO-PORT UP: 10 years
- Cuff: 20,000 cycles of reapplication

10 Order Information

PHYSIO-PORT UP PC System with

A20931 Battery charger with USB connection cable, and user manual

A20041 4 NiMH batteries

A20791 Power supply with European plug

A9934 Wearable pouch

A5171 Wearable pouch waist belt

A867 Connection cable PHYSIO-PORT UP to PC (USB), length approx. 1.5 meters

S2010 Connection cable PHYSIO-PORT UP to PC (RS232), length approx. 1.2 meters

A2500-m Blood pressure cuff, D-Ring for adults, Medium, for circumference between 24 cm and 32 cm, Rectus connector

S81390 PC Software PhysioPortWin and Operator Manual on USB-Stick

Optional Accessories and Combinable Medical Products for PHYSIO-PORT UP

A2500-s Blood pressure cuff, D-Ring for adults, Small, for circumference between 17 cm and 26 cm, Rectus connector

A2500-l Blood pressure cuff, D-Ring for adults, Large, for circumference between 32 and 42 cm, Rectus connector

A2500-xl Blood pressure cuff, D-Ring for adults, Extra-large, for circumference between 38 and 46 cm, Rectus connector

A20792 Three international plugs

S90381 Technical Inspection PHYSIO-PORT UP

EMC Compliant Cables and Accessories

Warning

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The list below shows the accessories that have been tested and found EMC compliant for use with PHYSIO-PORT UP.

Note

Any supplied accessories that would not affect electromagnetic compatibility (EMC) are not included.

A867 Connection cable PHYSIO-PORT UP to PC (USB), length approx. 1.5 meters

S2010 Connection cable PHYSIO-PORT UP to PC (RS232), length approx. 1.2 meters

11 Appendix – Electromagnetic Compatibility (EMC)

Changes or modifications to this system not expressly approved by PAR Medizintechnik could cause EMC issues with this or other equipment. This system is designed to comply with applicable regulations regarding EMC. Its compliance with these requirements has been verified. It needs to be installed and put into service according to the EMC information stated as follows.

Warning

Use of portable telephones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Warning

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
PHYSIO-PORT UP is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that PHYSIO-PORT UP is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions to EN 55011/ CISPR 11	Group 1	PHYSIO-PORT UP uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions to EN 55011/ CISPR 11	Class B	PHYSIO-PORT UP is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to EN 61000-3-2/IEC 61000-3-2	not applicable	
Voltage fluctuations/flicker emissions to EN 61000-3-3/IEC 61000-3-3	not applicable	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
PHYSIO-PORT UP is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that PHYSIO-PORT UP is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment— Guidance**
Electrostatic discharge (ESD) to EN 61000-4-2/ IEC 61000-4-2	±8.0 kV contact ±2.0 kV air ±4.0 kV air ±8.0 kV air ±15.0 kV air	±8.0 kV ±2.0 kV ±4.0 kV ±8.0 kV ±15.0 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst to EN 61000-4-4/ IEC 61000-4-4	±2.0 kV for power supply lines ±1.0 kV for input/output lines	not applicable not applicable	Mains power should be that of a typical commercial or hospital environment.
Surge to EN 61000-4-5/ IEC 61000-4-5	±0.5 kV differential mode ±1.0 kV differential mode ±0.5 kV common mode ±1.0 kV common mode ±2.0 kV common mode	not applicable not applicable	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to EN 61000-4-11/ IEC 61000-4-11	0 % power supply for 10 ms (0.5 cycles) 0 % power supply for 20 ms (1,0 cycles) 70 % power supply for 500 ms (25 cycles) 0 % power supply for 5000 ms (250 cycles)	not applicable not applicable not applicable not applicable	Mains power should be that of a typical commercial or hospital environment. If the user of PHYSIO-PORT UP requires continued operation during power mains interruptions, it is recommended that PHYSIO-PORT UP be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to EN 61000-4-8/IEC 61000-4-8	30.0 A/m	30.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
PHYSIO-PORT UP intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that PHYSIO-PORT UP used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment—Guidance**
Conducted RF to EN 61000-4-6 / IEC 61000-4-6 Radiated RF to EN 61000-4-3 / IEC 61000-4-3	3.0 V_{rms} 150 kHz bis 80 MHz 6.0 V_{rms} 150 kHz bis 80 MHz 10.0 V/m 80 MHz bis 2.7 GHz	3.0 V_{rms} 6.0 V_{rms} 10.0 V/m	Portable and mobile RF communications equipment should be used no closer to any part of PHYSIO-PORT UP, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ at 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ at 800 MHz to 2.7 GHz where *P* is the maximum output power rat-ing of the transmitter in watts (W) accord-ing to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electro-magnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which PHYSIO-PORT UP is used exceeds the applicable RF compliance level above, PHYSIO-PORT UP should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b) Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3.0 V/m.

Recommended separation distances between portable and mobile RF communications equipment and PHYSIO-PORT UP

PHYSIO-PORT UP is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of PHYSIO-PORT UP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and PHYSIO-PORT UP as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter [W]	**Separation Distance According to Frequency of Transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17 \sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.33 \sqrt{P}$
0.01	**0.12**	**0.12**	**0.24**
0.1	**0.37**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.34**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.34**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Patient Instructions

Keep the following points in mind to secure a safe and smooth operation of the device:

During each measurement stay relaxed and minimize your motion to keep the cuff inflation time as short as possible. If you are relaxed the pressure load to your arm will be minimized.

The trial measurement shows you the expected pressure load to your arm during the long term measurement. The pressure load to your arm will vary over the whole day. If the pressure rises far above the expected pressure, you are allowed to deflate the cuff by pressing the 

button or just remove the cuff from your arm.

Please note down all important events in a diary to secure a correct interpretation of your blood pressure values by the doctor. Please report all unexpected events or faults to your doctor.

Do not open the battery compartment. Protect the device against water, excessive humidity, and extreme temperatures and do not remove the device from the wearable pouch. Please wear the pouch over your clothes. You do not have to clean the device after the long term measurement. Sometimes the device internally stops the long term measurement. In this case deliver the device to the agreed date to your doctor.

The audio signals of the device are disabled by default. If the doctor enables the audio signals, the device will beep after power up procedure and in front of every measurement during day phase.

Place PHYSIO-PORT UP with the wearable pouch on your nightstand while you are sleeping. You are allowed to change the day phase and the night phase manually, if you go to bed before 10 pm or get up before 7 am. To change the phases press the 

button once. The results from the last blood pressure measurement are shown. Press the 

button once again, while the results are shown. The phase symbol switches from sun to moon or the other way around.

For your interest:

The device measures your systolic, diastolic and mean arterial blood pressure and your heartrate. The blood pressure is measured with an accuracy of ± 3 mmHg. The device can record up to 400 blood pressure measurements.

Note down here the additional instructions of your doctor:

A

B

C

D

E

F

G

I

M

N

O

P

R

S

T

U

W

CE 0482

PAR Medizintechnik GmbH & Co. KG
Rigistr. 11
12277 Berlin
Germany
Tel: +49 30 2350700

www.par-berlin.com

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