PHYSIO-PORT / PHYSIO-PORT AS

Recording Systems for Long-Term Blood Pressure Measurements and Pulse Wave Analyses

Firmware Version 3.0

Operator's Manual

A8135-ENG Revision C

Note

The information in this manual only applies to the devices PHYSIO-PORT and PHYSIO-PORT AS, and the trademark TENSIOPOD, each with firmware version 3.0. It does not apply to earlier firmware versions.

This manual was created with great care. In case you find details which do not correspond to the system please inform us so that we can resolve the discrepancies as soon as possible.

Due to continuing product innovation, specifications in this manual are subject to change without notice. To find out about the status of the latest version, please contact the manufacturer.

Printed in Germany

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Revision History

This manual is subject to the PAR Medizintechnik GmbH & Co. KG change order service. The revision index, a letter that follows the order number, changes with every update of the manual.

Order Number/Revision	Date	Comment
A8135-ENG Revision A	2018-03-05	Initial Release Establishment from the PHYSIO-PORT manual, revision of the document structure and addition of the product variant PHYSIO-PORT AS
A8135-ENG Revision B	2022-03-28	Changing of the address of the manufacturer
A8135-ENG Revision C	2023-02-03	Addition of the MDR compliance statement in the chapter *General Information*; Update of the intended use in Chapter 1.1; Correction of a translation error in the table head of table 1 in Chapter 9 (EMC); new symbols added in Chapter 2.1, Update of the data in Chapter 7, Update of the order information in Chapter 8, Addition of the device TENSIOPOD as trademark, Change of the battery charger

General Information

- The products **PHYSIO-PORT** and **PHYSIO-PORT AS** (short: ABPM devices) bear 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 fulfill the General safety and performance requirements of Annex I of this regulation. The device PHYSIO-PORT is also distributed under the trademark TENSIOPOD. 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 8 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 clinical validated. The validation fulfills the standard ISO 81060-2:2013 “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 will be enclosed in electronic form according to 207/2012 / EU. The data medium with the electronic manual or the manual in paper form, which can be requested free of charge from the manufacturer, must 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 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 Field 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 PAR Medizintechnik. 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 patients is established.

CE 0482

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The country of manufacture is indicated on the device label.

1 Application, Safety Information

1.1 Application

Intended Use

The ABPM devices are 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" fit the patient, it can be used on adults, children, and small children

In order to measure the blood pressure, a cuff is wrapped around the upper arm. The blood pressure is measured by the oscillometric method, during the deflation of the cuff (deflation method).

The device additionally can measure the blood pressure measurement during the inflation of the cuff (inflation method).

The choice between the inflation and the deflation method is done during the preparation of the device, either directly on the device or by using the corresponding PC software.

The heart rate is measured from the time distances of the maximal pressure oscillations occurring in the rhythm of the heartbeat.

The devices support the physician in the diagnosis and supervision of pathophysiological blood pressures like hypertension or hypotension. To establish a diagnosis the measurement values should be combined with other measurements and physical examinations of the patient.

The intended patient populations for the blood pressure measurement are adults (including pregnant women), children and infants but not neonates, with a circumference of the upper arm in the range of 17 to 46 cm. The appropriate approved cuffs have to fit to the upper arm circumference. The cuffs are wrapped around the uninjured upper arm, so that they come in contact only with intact skin.

The devices are not intended to be used in intensive care medicine or for raising alarm in life-threatening conditions. The application of the cuff is prohibited on an arm with a dialysis shunt, fresh operation wounds, or mastectomy.

If the doctor ascertains a positive benefit-risk ratio, the application of the cuff is allowed on the arm with a lymphedema, a paresis or an arterial or venous vascular access.

A measurement has to be performed at rest.

The devices are available on prescription in health care medicine and are intended for use following a consultation and instruction of the patient by a physician (family doctor, specialist or hospital). They can be used if the physical condition of the patient allows an automatic, non-invasive blood pressure measuring under his observation. Medically trained staff like a doctor or nurse, etc. should do this judgement as well as the accommodation of the patients and the preparation and application of the device. The device can be applied to the patient during day and night time. The patient does not operate with the device by himself.

A long term observation of the blood pressure is limited by the battery charge or the maximal number of 400 measurement values which can be stored. The devices are intended to measure and store the blood pressure in different programmed intervals. The programming is done by using the corresponding PC-software or by selecting one of three predefined measuring protocols.

The variant AS can additionally perform a long-term or single pulse wave analysis (PWA). During an additional holding phase after the blood pressure measurement, the central blood pressure and the pulse wave velocity are determined in a non-invasive way. This feature can be switched off, therefore, it is optional.

The additional possibility of a PWA supports the physician in the diagnosis and supervision of pathophysiological vascular changes.

The intended patient populations for the pulse wave analysis are adults older than 18 years, with a circumference of the upper arm in the range of 17 to 42 cm.

The variant AS is not determined for measurement of patients with arrhythmias or acute arterial occlusive disease.

It can store a maximal number of 100 pulse wave analyses.

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 or its re-presentative.

Note

For the visualization of the long-term measurement results, the software PhysioPortWin as of version 1.5 can be used.

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 determined either during deflation of the cuff (deflation measurement method) or, by using a novel and faster technology, already during inflation of the cuff (inflation measurement method).

The deflation measurement method is the most 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).

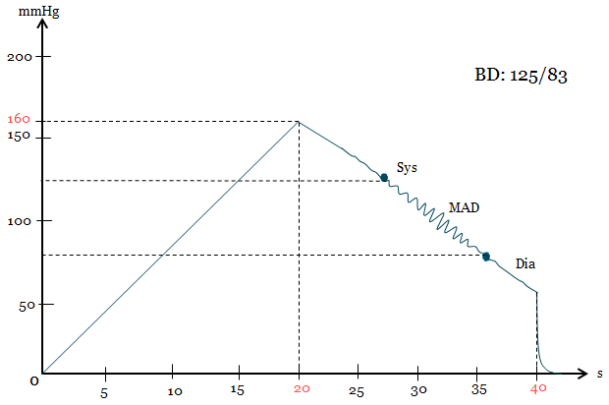


Fig. 1-1 Waveform representing the pressure in the cuff during a measurement using the deflation measurement method: systolic pressure at 125 mmHg, diastolic pressure at 83 mmHg

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, the PHYSIO-PORT devices will automatically switch to the deflation measurement method and complete the blood pressure measurement.

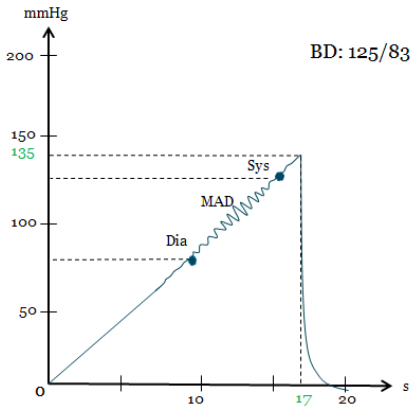


Fig. 1-2 Waveform representing the pressure in the cuff during a measurement using the inflation measurement method: systolic pressure at 125 mmHg, diastolic pressure at 83 mmHg

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.

The Pulse Wave Analysis

Electively, the variant PHYSIO-PORT AS (**A**rterial **S**tiffness) can conduct a pulse wave analysis following a non-invasive blood pressure measurement. If elected, the pulse wave analysis is performed right after one of the two blood pressure measurement methods. For this, the measured mean arterial pressure level (MAD) is set in the cuff and the pulses in the cuff are recorded for a fixed period of time (see Fig. 1-3). Disturbances are removed from the recorded pulses. From the usable pulses, the pulse that is located centrally at the heart is reconstructed non-invasively to determine the central blood pressure and the pulse wave velocity. Both parameters can be used by the physician to estimate the patient-specific state of the vessels.

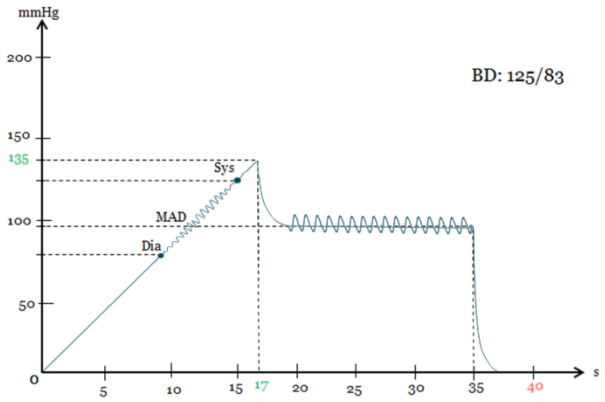


Fig. 1-3 Waveform representing the pressure in the cuff during a measurement using the inflation measurement method with subsequent pulse wave analysis

1.2 Functional Description

The ABPM devices accommodate 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 devices are powered by two AA size batteries (either rechargeable NiMH batteries or alkaline batteries).

The variant PHYSIO-PORT AS holds an additional high-performance circuit board (PWA module) which is integrated in the basic version PHYSIO-PORT in order to perform the pulse wave analysis. This board has its own microprocessor and works only on command from the PHYSIO-PORT main system whereby the additional function has no influence on safety-relevant features of the basic version.

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 (N2O), 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. In those instances where there is any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts to find out whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of equipment. The standards IEC 60601-1 or IEC 60950-1 must be observed in any case.***

– ***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 device to another port of the PC can lead to interference during data transfer)***
  - ***disconnection of items***
  - ***update or upgrade of equipment***

– ***ABPM devices may be connected to a PC with PhysioPortWin. While the devices are connected to a PC, they have to 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.***

Warning

Risk to Persons —

- ***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.***
- ***Before cleaning, the device must be dis-connected from other equipment (e.g. a 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 the device 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.***

2 Controls and Indicators

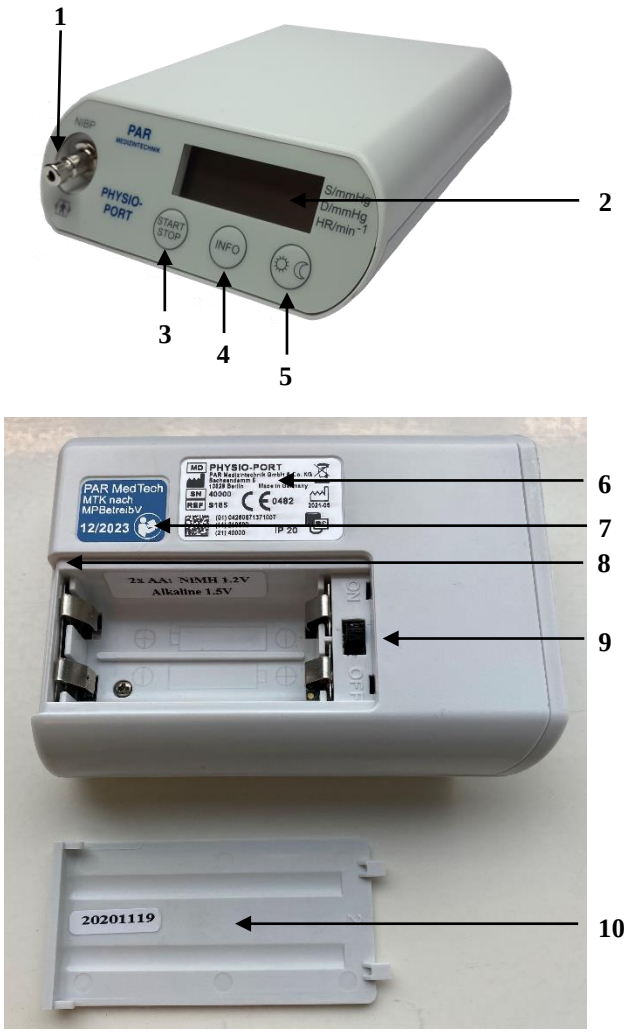


Fig. 2-1 Controls and indicators of the *ABPM devices*

Fig. 2-2 Nameplates of the ABPM devices

1 *Connection for blood pressure cuff*

2 *Liquid crystal display (LCD)*

3 *Button* (START STOP)

4 *Button* (INFO)

5 *Button*

6 *Nameplate*

7 *Calibration mark*

8 *Port for connection to PC (USB) at the rear of the device*

9 *On/off switch*

10 *Lid covering battery compartment*

Button Functions

During a long-term measurement the buttons on the device have the following functions:

START STOP	To start and stop a measurement and to confirm entries
INFO	To display the most recent measurement values or error message. Systolic value „S“, diastolic value „D“ and pulse rate „HR“ are displayed successively. To mark an event, push the info button while the measured values are being displayed. As confirmation, “1111” will be shown on the LCD display. The related measurement will be marked in the measurement value table.
	To manually switch the measure interval between the day phase and the night phase (see section „ Toggling Between Day and Night Phase “)

Note

The manual switching between day and night phases is only possible if two measure intervals were programmed when the ABPM device was started with the PhysioPortWin software and the day/night button has not been deactivated.

If more or less than two measure intervals have been set, the day/night button does not have an influence on the measure intervals.

2.1 Explanation of Signs and Symbols

Symbols used on the equipment and on the packaging

Follow the instructions given in the operator 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)

Reference number

Serial number

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

Manufacturer's identification

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

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

NIBP — Connector for the blood pressure cuff

Quantity

Temperature limits

Humidity limits

Air pressure limits

Ambulant Blood Pressure Measurement Device

PC System Ambulant Blood Pressure Measurement Device

Symbols used on the display

M — 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

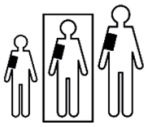
Protection class II equipment

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.

2.2 Connections

Connection of the blood pressure cuff

To connect the blood pressure cuff with the device, the metal connector on the cuff has to be pushed onto the connecting piece on the device until it clearly engages. (see Fig. 2-3).

Fig. 2-3 Cuff connection of the ABPM devices

By pulling the cuff connector's outer metal sleeve back, the blood pressure cuff can be disconnected from the device.

Connection to PC

To start and program as well as read stored measuring data, the device needs to be connected to the PC via a mini-USB connection cable (see Fig. 2-4). This USB cable is connected to a free USB port of the computer.

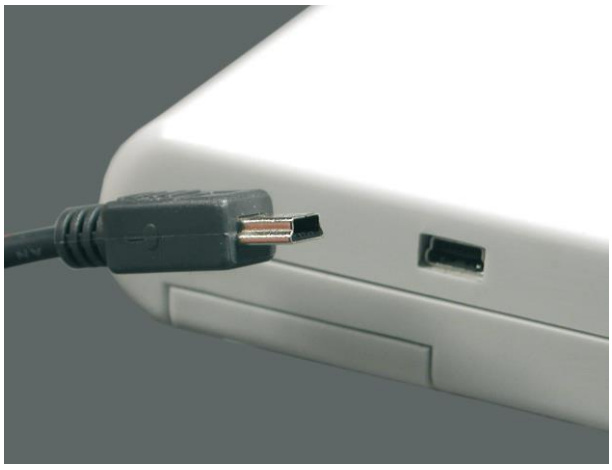


Fig. 2-4 Connection of the mini-USB connection cable

Note

To start and program the device prior to a measurement as well as to read and analyse the data after a measurement, an additional evaluation software (e.g. PhysioPortWin) is required.

3 Setup

3.1 Basic Facts about the Battery Supply

The ABPM devices are powered either 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"). Moreover, the device 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 the ABPM devices are out of use for one month or longer, 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.***

3.2 Inserting Batteries

- Open the battery compartment on the back of the ABPM devices (see Fig. 3-1).

Fig. 3-1 Opening the battery compartment

- Place the two batteries in the compartment as indicated by the symbols (see Fig. 3-2).

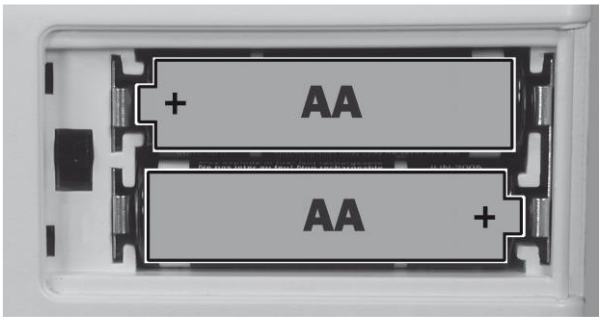


Fig. 3-2 Observe the polarity of the batteries.

Note

Observe the correct polarity when inserting the batteries.

3.3 Selecting the Energy Source

- When starting the recorder, the used energy source needs to be set via the PC software PhysioPortWin.

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.

3.4 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 the ABPM devices are 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 (see Fig. 3-3 and 3-4).

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

Fig. 3-4 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 socket.
- Insert the two rechargeable batteries into the charging unit, observing the correct polarity.

3.5 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.

3.6 Switching ABPM Devices ON and OFF

The ABPM devices have a power switch inside their battery compartment. Open the battery compartment (see Fig. 3-1) and turn the device on and off as follows, if (rechargeable) batteries have been inserted:

To switch ON: Slide the switch to ON.
To switch OFF: Slide the switch to OFF

3.7 Performance Check

When turned on, the ABPM devices run a self-test that includes all symbols and segments on the LCD (Fig. 3-5). Then, the version number of the device software is displayed (e.g. „P 30“ for version 3.0).

Afterwards, the device checks the inserted (rechargeable) batteries and indicates the remaining capacity (see Fig. 3-6). "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. 3-7).

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

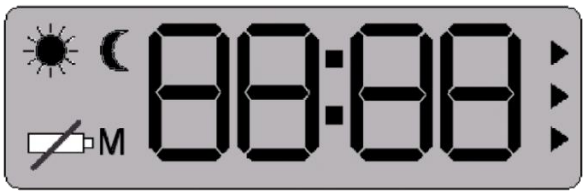


Fig. 3-5 Test display on LCD

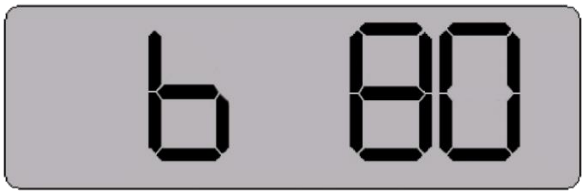


Fig. 3-6 Battery capacity of 80 %

3.8 Clock Display

Each time the device is started by the PC software, the clock, which is integrated into the device, is automatically set to the PC time (see Fig. 3-7). Manually changing the time at the device is not possible.

*Fig. 3-7 Example: Display after successful self-test (**M** = BP data in memory, ☀ measuring phase: day)*

4 Application

4.1 Applying the cuff

Warning

Risk to Persons —

The ABPM devices must not be connected to other equipment (e.g. PC) when the cuff is applied 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.

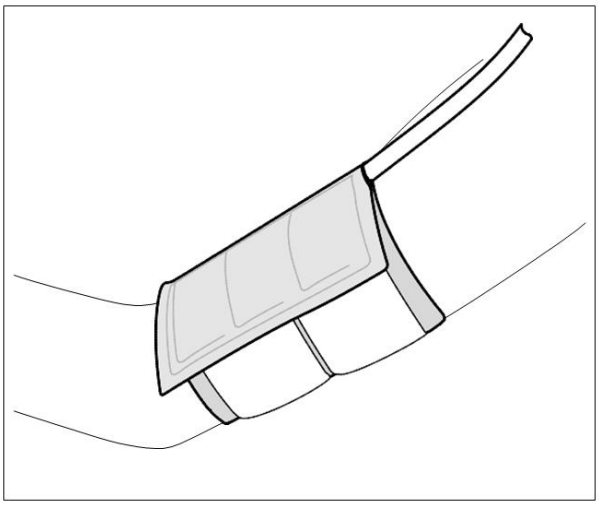


Fig. 4-1 Applying the cuff

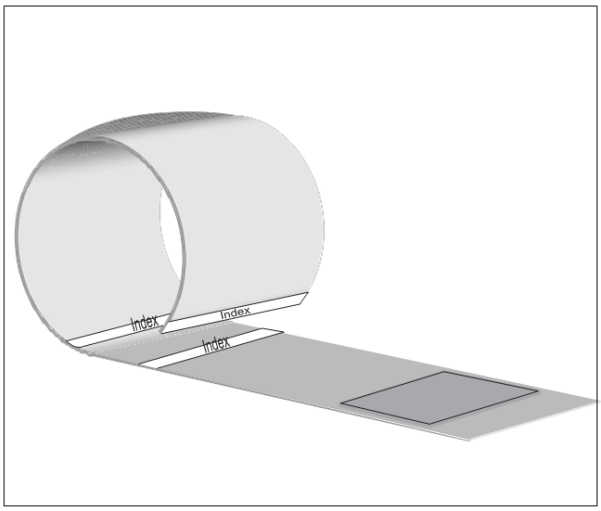


Fig. 4-2 Applying the cuff

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 ABPM device 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.***
- ***Select the appropriate cuff size as a cuff that is too small will lead to overrated BP values and when the cuff is too big, the measured values will be too low.***

- 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 towards the shoulder (Fig. 4-1),
- no compression or restriction of connection tubing can occur
- the arrow is located above the brachial artery
- the dashed white line at the end of the cuff is located between the two dashed 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 ABPM devices are used inside the ambient conditions for operation and inside the measuring range (s. chapter „Technical Specifications“)

4.2 Performing a Trial Measurement

Note

Before using an ABPM device, the data in the memory must be deleted, the time and date checked and, if wrong, corrected, the desired measuring program must be selected and the signal transmitter switched on or off if necessary. The product variant PHYSIO-PORT AS does not have a signal transmitter. An additional evaluation program (e. g. PhysioPortWin) is required for these activities when starting and programming.

- Switch on the ABPM device 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 the ABPM device (see Fig. 2-3). 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.
- **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). If PHYSIO-PORT AS is used and the pulse wave analysis has been activated, the measured mean arterial pressure level (MAD) is set and held in the cuff for 15 seconds, directly after the blood pressure measurement has been performed. Only then will the cuff pressure be released completely. The respective measured cuff pressure is indicated on the display.
  The following values are displayed at the end of the measurement:
  - the systolic readings (S in mmHg)
  - the diastolic readings (D in mmHg) and
  - the pulse rate (HR/min^{-1}).
- If an error code 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.

4.3 Patient Information

Advise your patient

- **not to move, not to talk, stay relaxed and breath normally while a measurement is being taken to avoid artifacts that may lead to erroneous readings and to keep the cuff inflation time as short as possible**
- to place the ABPM device 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“),
- that important events like driving by car or using public transport, because this can cause artificial oscillations and consequently false readings, plus stress situations should be noted down in a diary that you can interpret the results correctly,
- not to perform excessive sport within the long-term measurement
- 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 31).

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 plegie
- arterial or venous vascular access

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

Note

The professional healthcare personnel have to give some information about the accuracy of the ABPM devices to the patient.

4.4 General Information on Ambulatory BP Measurement

It is recommended to operate the device in the mode „activated inflation measurement“. This mode significantly shortens the measurement time of an individual measurement and therefore offers greatly increased comfort with significantly reduced stress for the patient.

A manual measurement can be taken at any time between the automatic measurements. Manual measurements are marked with “+” in the measurement value table.

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 “E04” (battery depleted), “E07” (inflation time over) and “E10” (400 blood pressure measurements taken) do not lead to a second measurement. The next measurement after error code “E07” occurs at the selected interval.

After error codes “E04” and “E10”, the device enters the power-save mode to prevent over-discharging of the re-chargeable batteries. This mode can only be terminated by turning the device off and on again.

Deflation Measurement Method:

If “activated inflation measurement” is not activated by putting a checkmark, the ABPM device operates in the conventional „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 25 mmHg above the systolic value of the previous measurement (minimum inflation pressure: 120 mmHg).

The determination of the blood pressure values takes place when the cuff pressure is gradually decreased.

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 about 20 mmHg above the determined systole and then immediately vents the cuff completely.

Pulse Wave Analysis

With the PHYSIO-PORT AS it is possible to combine the pulse wave analysis with both blood pressure measurement methods. The holding pressure after the blood pressure measurement is equal to the measured mean arterial pressure level (MAD).

4.5 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 INFO 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.

4.6 Audio Signal (optional)

If the buzzer is available and enabled, the audio signal will be emitted in the following situations:

- shortly after the ABPM device has been switched on
- just before the ABPM device starts inflating the cuff (during the day phase only)
- after the ABPM device has detected an erroneous measurement

5 Error Codes

E 03 Internal hardware error. Please contact your local authorized dealer (http://www.par-berlin.com).

E 04 Batteries depleted. Code appears when the battery capacity is insufficient for new BP measurements.

E 05 Measurement time over. Code is displayed after measurement duration of 180 seconds (without inflation time).

E 06 This code appears when

- the current cuff pressure would exceed the maximum permissible inflating pressure of 280 mmHg,
- the device has reached the selected maximum inflating pressure,
- a measurement is not possible (device waits until the next time of measurement).

E 07 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 08 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 the ABPM devices automatically switch to the deflation measurement method if the number of detected oscillations is insufficient.

E 09 Internal hardware error. Please contact your local authorized dealer.

E 10 Memory space is full. 400 pressure measurements have been taken and thus the storage capacity is exhausted.

E 11 Motion artifact during diastole detection.

E 12 Diastolic reading outside measuring range.

E 13 Internal hardware error. Please contact your local authorized dealer.

E 20 Systolic reading outside measuring range. (Codes E12 and E20 are displayed when the systolic and diastolic values are outside the range in which oscillations were detected.)

E 21 Systolic reading below measuring range.

E 22 Systolic reading above measuring range.

E 23 Motion artifact during systole detection, air discharge speed too high, e. g. due to leakage.

E 24 Difference between systolic and diastolic pressure too small (10 mmHg or less).

6 Cleaning, Maintenance, Disposal

6.1 Cleaning and Disinfection of the Equipment Surface

Warning

Shock Hazard —
Disconnect the ABPM device from the PC or printer before cleaning.

- Switch off the ABPM device.
- 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. werden.

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

6.2 Cleaning and Disinfection of the Cuffs

- Light staining can be wiped off with a damp cloth.
- In case of heavy staining, wash the cuff with soapy water or disinfectant detergent (not in the washing machine). No liquid may penetrate into the cuff bladder or the connecting hose.
- After the application, 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).
- After cleaning, rinse the cuff thoroughly with clean water and let it dry in the air at room temperature for about 15 hours.

6.3 Cleaning and Disinfection of 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.

6.4 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.

The ABPM devices represent a measuring device, which is why they must be subjected to a regular “Technical Safety Inspection" and “Technical Inspections of the Measuring System" in accordance with MPBetreibV § 11/ Annex 2. The time of the next due inspection is indicated by the calibration seal (see Fig. 2-1).

Technical Safety Inspections

- For safety, the device requires regular maintenance. To ensure functional and operational safety of the ABPM devices, Technical Safety Inspections should be carried out at least every two years.

Caution

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

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

The nature and extent of the inspections are described in the corresponding sections of the Service Manual.

Upon request, PAR Medizintechnik provides a Service Manual.

The device does not require any other maintenance.

Technical Inspections of the Measuring System

- The non-invasive pressure measurement system of the ABPM devices should be inspected every two years.

Caution

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

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

The nature and extent of the inspections are described in the corresponding sections of the Service Manual.

Upon request, PAR Medizintechnik provides a Service Manual.

6.5 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.

7 Technical Specifications

Measuring Method

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

Measuring Interval

– 2 - 120 min, programmable

Maximum cuff pressure

– 300 mmHg

Interfaces

– USB (HID)

Dimensions

– Height: 27 mm
– Width: 80 mm
– Depth: 105 mm

Battery

– 2 Mignon (size AA) rechargeable NiMH batteries, 1,2 V, > 1.500 mAh or
– 2 Mignon (size AA) alkaline batteries

Battery Charge Time

– 2…3 hours

Battery Charger

– protection class II, IP20
– 100…240 VAC 50/60 Hz, 0.5 A

Ambient Conditions

Operation

– temperature + 0 °C …+ 55 °C
– relative humidity 15…93 %, no condensation
– atmospheric pressure between 700…1060 hPa
– altitude (relative to sea level) -400…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…+70 °C
– relative humidity 10...93 %, no condensation
– atmospheric pressure 500...1060 hPa
– altitude (relative to sea level) -400…4500 m

Protection Class

– IP20: ABPM device
– IP02: wearable pouch of the ABPM device
– IP22: ABPM device in wearable pouch

Expected Service Life

– ABPM device: 10 years
– Cuff: 20.000 cycles of reapplication

7.1 Blood Pressure Measurement

Measuring Range

– systolic pressure	60…260 mmHg
– diastolic pressure	40…220 mmHg
– mean pressure	45…250 mmHg
– pulse rate (HR)	35…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
pulse rate (HR):	1.0 ± 2.6 min^{-1}

– 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

Weight

– < 225 g, incl. batteries

7.2 Pulse Wave Analysis (PHYSIO-PORT AS)

Measuring Range

– central systole	80…200 mmHg
– central diastole	50…120 mmHg
– pulse wave velocity	4.5…16.0 m/s

Measurement Accuracy (of the corresponding central systolic and diastolic pressure in the A. ascendens)

central systole:	0.2 ± 3.6 mmHg
central diastole:	-0.7 ± 0.9 mmHg
pulse wave velocity	-0.2 ± 1.2 m/s

Measurement Capacity

– up to 100 pulse wave analyses

Weight

– < 225 g, incl. batteries

8 Order Information

The following components are part of the ABPM PC systems:

Using the item number all system components can be obtained from the manufacturer.

Recording Device

S1851	PHYSIO-PORT
S1853	TENSIOPOD
S285	PHYSIO-PORT AS

Standard Delivery Package

A867	Connection cable to PC
A20931	Battery charger with USB connection cable, and user manual
A20041	4 NiMH batteries
A20791	Power supply with European plug
A2206	Wearable pouch with shoulder strap
A5171	Belt for wearable pouch
A2500-m	NIBP UP® LZBD Cuff Medium (24…32 cm) with D-ring (PHYSIO-PORT/ PHYSIO-PORT AS)
S81390	PC Software PhysioPortWin and Operator Manual on USB-Stick

Optional Accessories and Combinable Medical Products for PHYSIO-PORT / PHYSIO-PORT AS and its trademarks

A2500-s	NIBP UP® LZBD Cuff, Small (17…26 cm) with D-ring
A2500-l	NIBP UP® LZBD Cuff, Large (32…42 cm) with D-ring
A2500-xl	NIBP UP® LZBD Cuff, Extra-large (38…46 cm) with D-ring
A2523-xs	NIBP UP® LZBD Cuff Extra-small (13…20 cm)
A2523-s	NIBP UP® LZBD Cuff Small (17…26 cm)
A2523-m	NIBP UP® LZBD Cuff Medium (24…32 cm)
A2523-l	NIBP UP® LZBD Cuff Large (32…42 cm)
A2523-xl	NIBP UP® LZBD Cuff Extra-large (38 …46 cm)
A20792	Three international plugs
S90391	Technical Inspection PHYSIO-PORT

Note: If the packaging or the content is damaged, please contact the customer service.

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 the ABPM devices (see Appendix - Electromagnetic Compatibility (EMC)).

Note

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

A867	Connection cable to PC (USB), length approx. 1.5 m

9 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 com- ply 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 used.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The ABPM devices are intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ABPM devices are used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidelines**
RF emissions to EN 55011/ CISPR 11	Group 1	The ABPM devices use 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	The ABPM devices are 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			
The ABPM devices are intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ABPM devices are 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 inter-ruptions and voltage varia-tions on power supply input lines to EN 61000-4-11/ IEC61000-4-11	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 the ABPM devices requires continued operation during power mains interruptions, it is recommended that the ABPM devices are 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

The ABPM devices are intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ABPM devices are 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	3.0 V_{rms} 150 kHz bis 80 MHz 6.0 V_{rms} 150 kHz bis 80 MHz	3.0 V_{rms} 6.0 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the ABPM devices, 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 rating of the transmitter in watts (W) according 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 
Radiated RF to EN 61000-4-3 / IEC 61000-4-3	10.0 V/m 80 MHz bis 2.7 GHz	10.0 V/m	

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 the ABPM devices are used exceeds the applicable RF compliance level above, the ABPM devices should be observed to verify normal operation. If abnormal per-formance 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 the ABPM devices

The ABPM devices are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ABPM devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ABPM devices 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 do not to move, do not to talk, stay relaxed and breathe normally to keep the cuff inflation time as short as possible. If you are relaxed the pressure load to your arm will be minimized. The device is not intended to be used when you are performing excessive sport within the long-term measurement.

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 START STOP 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 available. 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 the ABPM device 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 INFO button once. The results from the last blood pressure measurement are shown. Press the INFO 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 PHYSIO-PORT AS can additionally perform a pulse wave analysis and thereby determine the central systolic and central diastolic blood pressure as well as the pulse wave velocity. The blood pressure is measured with an accuracy of ± 3 mmHg and the pulse wave velocity is determined with an accuracy of 1.5 m/s. The device can record up to 400 blood pressure measurements.

Note down here the additional instructions of your doctor: