# IEM®

# Mobil-O-Graph

Instructions for Use EN

Mobil-O-Graph® PWA
Long-term blood pressure monitor with pulse wave analysis (PWA)

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician

Evaluation unit:
Hypertension Management Software CS (HMS CS)

CE 0044

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# 1 Introduction

## 1.1 Preliminary note

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Thank you for choosing the long-term blood pressure monitor Mobil-O-Graph® with the 24-hour pulse wave analysis (PWA) option. The blood pressure measuring device has been specially developed for 24-hour measurement and works according to the oscillometric measuring principle. The 24-hour pulse wave analysis can be activated at any time in a variety of configurations using a licence key and the Hypertension Management Software Client Server (HMS CS).

In practice, you can prepare the Mobil-O-Graph®, also referred to below as the blood pressure monitor, for a new patient in a few minutes. This gives you the advantage of being able to use the blood pressure monitor optimally and to conduct a 24-hour profile for each day. The Mobil-O-Graph® will thus be quickly integrated into your everyday practice. The Hypertension Management Software Client Server (HMS CS) helps you to manage your blood pressure data and allows you to analyse and evaluate the blood pressure measurements.

## 1.2 About these instructions for use

These instructions for use will ensure that you become familiar with the long-term blood pressure measuring device and the accessories. With a little practice you will find out how easy the blood pressure monitor is to use.

The readings are evaluated using Hypertension Management Software Client Server data management, which is included on the CD together with the software handbook.

Please refer to the HMS CS instructions for use for software operating instructions.

These instructions for use explain the blood pressure monitor and accessories in the order in which you will operate the device and also use later.

The individual functions are not explained until they are needed. You will therefore be familiarized with the blood pressure monitor on a step-by-step basis.

**The instructions for use should be kept for future use and must always be available to the user!**

## 1.3 Clinical trials

The Mobil-O-Graph® fulfils the requirements of the ESH (European Society of Hypertension), BHS (British Hypertension Society) and ISO 81060-2:2013.

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## 1.4 CE Mark

The Mobil-O-Graph® fulfils the requirements of the

- 93/42/EEC (MDD),
- 2014/53/EU (RED),
- 2011/65/EU (RoHS) Directives

and bears the CE Mark.

IEM GmbH hereby declares that the Mobil-O-Graph® corresponds to the 2014/53/EU Directive.

The complete text of the EU declaration of conformity is available at the following website address: https://www.iem.de/doc/.

# 2 Instruction notes

## 2.1 Intended use

The intended use is 24-hour blood pressure measurement and pulse wave analysis (PWA).

The Mobil-O-Graph® is only to be used under medical supervision by medical personnel.

## 2.2 Improper use

- The Mobil-O-Graph® must not be used for any purpose other than the process of measuring blood pressure described herein.
- Due to the risk of strangulation by the tube and cuff, the Mobil-O-Graph® must not be used on patients of unsound mind and must not be left within reach of unsupervised children.
- The Mobil-O-Graph® is not intended for use on babies and children under the age of 3.
- The Mobil-O-Graph® is not intended for use on women who are pregnant or those with pre-eclampsia.
- The Mobil-O-Graph® must not be used for alarm-triggering blood pressure monitoring during operations or in intensive care units.
- The Mobil-O-Graph® must not be used on airplanes!

## 2.3 Essential performance features

The essential performance features are defined as blood pressure measurement with:

- Error tolerances of the pressure gauge and measurement results within the required limits according to IEC 80601-2-30
- Maximum change value in blood pressure determination according to IEC 80601-2-30
- Power delivery (pressure supply to the cuff) within the set limits according to IEC 80601-2-30
- An error is issued if successful blood pressure measurement is not possible.

The device does not trigger any alarms in the sense of IEC 60601-1-8 and is not intended for use together with HF surgical devices or for clinically monitoring patients, e.g. in an intensive care unit.

In the event that the status or configuration of the device is unclear, the device will go into a safe operating mode, which causes the device to release the air from the cuff.

The cuff is not automatically pressurised; to do so, the device must be initiated manually.

## 2.4 Indication

The Mobil-O-Graph® is intended to clarify the blood pressure situation and for diagnosis support. The field of application is domestic healthcare and professional facilities such as doctor's practices and medical centres.

The doctor may, at his own discretion, carry out an appropriate examination on his patients with this medical system if, among other things, they:

- are hypotensive or
- are hypertensive,
- require antihypertensive therapy,
- suffer from myocardial hypertrophy or
- suffer from nephrological dysfunction.

## 2.5 Side effects of long-term blood pressure measurement

Long-term blood pressure measurement is a commonly practised and valued measurement technique, and has found its way into daily diagnostics and treatment monitoring.

Blood pressure measurement can lead to petechial bleeding or haematomas on the measuring arm despite the correct positioning of the cuff in case of coagulation disorders, taking anticoagulants or in the case of sensitive body tissue. Always check whether the patient has coagulation disorders or is undergoing anticoagulant treatment. The patient-dependent risk resulting from anticoagulant treatment or in patients with coagulation disorders arises irrespective of the type of measuring device.

## 2.6 Safety

Read the safety instructions carefully before using the products! It is important that you understand the information in these instructions for use. If you have any questions, please do not hesitate to contact technical support.



### 2.6.1 Defining the signal words used

In order to point out dangers and important information, the following symbols and signal words are used in these instructions for use:

WARNING

**Short description of the danger**

This warning symbol in connection with the signal word **WARNING** indicates a possible or immediately threatening danger.

Non-adherence may lead to mild, moderate to severe injuries or to death.

ATTENTION

**Short description of the danger**

This warning symbol, in connection with the signal word **ATTENTION**, indicates possible material damage.

Non-adherence may lead to damage to the products or their accessories.

### 2.6.2 Defining general notes

**Note**

The signal word **Note** indicates further information about the Mobil-O-Graph® or its accessories.

**External reference**

Indicates reference to external documents in which further information may optionally be found.

## 2.7 Important safety instructions for the doctor

**WARNING**

**Danger of blood flow interruptions as a result of constant cuff pressure or as a result of too frequent measuring**

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Ensure the shoulder strap and cuff tube are in the correct position and take care that the cuff tube is not knotted, squashed or stretched.
- Do not kink the cuff tube.
- Always put the cuff tube under clothing (even at night).
- Be sure to tell patients about the correct positioning of the cuff and point out to them that the device is to be placed in such a way that the inflated cuff is not squeezed or kinked, especially when sleeping.
- Measurement can be interrupted at any stage by pressing any button. This deflates the cuff and the device can be removed.
- Inform the patient about this danger.

**WARNING**

**Risk of strangulation by shoulder strap and cuff tube**

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- The Mobil-O-Graph® must not be used on patients of unsound mind.
- If the Mobil-O-Graph® is used on children, this should be done with particular caution and under the constant supervision of the doctor in accordance with regulations.
- Do not place the shoulder strap and cuff tube around the patient's neck.
- Instruct the patient to wear the cuff only on the upper arm and, in any case, to make sure that neither the shoulder strap nor the pressure tube could ever wrap around the neck. For this purpose, the air tube is always laid under the outer clothing (even at night).
- Be sure to tell patients about the correct positioning of the cuff.
- Instruct the patient to turn off the device, remove the cuff and inform you if they are experiencing any pain, swelling, redness or numbness in the arm around which the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)
- Measurement can be interrupted at any stage by pressing any button. This deflates the cuff and the device can be removed.

**WARNING**

**Risk of injury if used on patient groups for whom this device is not intended**

- The Mobil-O-Graph® is not intended for use on women who are pregnant or those with pre-eclampsia.

**WARNING**

**Risk of injury from putting on and pumping up a cuff over a wound**

- Do not place the Mobil-O-Graph® over a wound or bandage.

**WARNING**

**Danger of a temporary loss of function of a present electrical medical device as a result of putting on or pumping up a cuff when the patient is wearing a further electrical medical device for monitoring on the same limb.**

- Only put the Mobil-O-Graph® on if the patient is not wearing any other electrical medical device on their arm.

**WARNING**

**Danger of injury and danger of blood flow disruptions as a result of putting on and pumping up a cuff on limbs with an intravascular drip or intravascular treatment or with an arteriovenous (AV) shunt.**

- Do not put the Mobil-O-Graph® on anyone who has an intravascular drip or arteriovenous (AV) shunt in their arm.

**WARNING**

**Danger of injury as a result of allergic reactions to the cuff material**

- The printing ink contains epoxy resin. In hypersensitive patients, the ink can cause allergic reactions in very rare cases.
- Let your patients know that they should turn the device off and take off the cuff in the event of any pain or allergic reactions.
- Follow hygiene procedures according to the maintenance plan.

**WARNING**

**Danger of injury as a result of using unapproved accessories**

- Only use accessories approved and distributed by the manufacturer.
- Read the respective information provided by the manufacturer before using the accessories for the first time.
- Check accessories in relation to the manufacturer's specifications before use.
- Instruct the person to be measured to switch off the device immediately, remove the cuff and to inform you if they experience any pain.

**WARNING**

**Risk of petechiae, haemorrhages or subcutaneous haematoma**

- Make sure that the use of the device does not result in impaired blood circulation in the arm due to the patient's state of health.
- Tissue bleeding or haematoma can occur in patients with sensitive body tissue despite proper positioning.
- Find out if the patient is taking anticoagulants or suffers from coagulation disorders.

**WARNING**

**Danger of injury as a result of putting on or pumping up a cuff on an arm on the same side of the body on which a mastectomy has been carried out**

Do not put the Mobil-O-Graph® on a person's arm that is on the side where a mastectomy has been carried out.

**! ATTENTION**

**Damage to the device**

- Liquid must not get into the device. If you think that liquid has entered the device during cleaning or use of the device, the device must not be used any more.
- If the device is exposed to moisture, switch the device off and remove the batteries. Be sure to inform technical support or send the device to your specialist supplier or manufacturer.
- The device must not be used in the vicinity of a magnetic resonance imaging apparatus or in the direct proximity of another electrical medical device.
- The Mobil-O-Graph® is not suitable for simultaneous use with high-frequency surgical devices.
- Do not drop the device and do not place objects on top of it.
- Do not use the device directly adjacent to other devices or stacked with other devices, as this may result in malfunction. If it nevertheless becomes necessary to use the device in the manner described above, this device and the other devices should be monitored to ensure that they are functioning correctly.
- The use of components other than those supplied with the product may lead to measurement errors, as alternative transformers and cables, for example, may increase electromagnetic interference emissions or reduce electromagnetic immunity. You should therefore only use IEM accessories.
- The device must not be connected to a PC or other device when it is still electrically connected to a patient.
- Measurement can be interrupted at any stage by pressing any button. This deflates the cuff and the device can be removed.
- Remove the batteries or power pack from the battery compartment as soon as they have run out of charge or if you do not expect to use the measuring device for a long period of time.
- The cuff and tube are made of a material that does not conduct electricity. They therefore protect the device against the effects of discharging a defibrillator. In the event of discharging a defibrillator, the

device itself must not touch the patient since the device can be damaged as a result of this discharging which may result in incorrect values being displayed.

- Extreme temperatures, humidity or air pressure can influence measurement accuracy. Please follow the instructions for use.
- The Mobil-O-Graph® fulfils all requirements of the EMC standards, but the Mobil-O-Graph® should not be exposed to strong electromagnetic fields as this may cause malfunction outside the limits. You should therefore ensure that the Mobil-O-Graph® is at least 30 cm (12 inches) from any portable RF communication devices.
- Do not open the casing of the Mobil-O-Graph®, otherwise any warranty will no longer be valid.
- Do not attempt to recharge the batteries. Do not attempt to open or short-circuit the batteries/rechargeable batteries. There is a risk of explosion.

**Note**

- Pulse wave analysis provides additional indicators of potential risks, but is not valid as a sufficient indicator of individual illnesses or recommendations for treatment.
- It should be noted that the use of pulse wave analysis in children currently has no clinical trials against reference methods.
- External interference factors, such as movement of the arm being measured, physical activity, driving or using public transport during measurements, may result in movement artefacts or incorrect measurements. When evaluating measurement results, you should therefore consult the record kept by the patient and take this into account in your evaluation.

**Note**

Electrostatic discharges, such as discharges of synthetic textile clothing, can trigger a reboot of the device. The same behaviour occurs when the internal memory batteries are empty and the external batteries are replaced. Here, the device starts in the last used operating state.

The appendix contains important information for the patient. This patient information can also be found in DIN A4 format at https://www.iem.de/en/patient-information/.

If necessary, you can print it out and give it to the patient.

# 3 Product description

## 3.1 Description

The ambulatory blood pressure monitoring consists of two main components:

- the Mobil-O-Graph® monitor with various cuffs and additional accessories.
- the Hypertension Management Software Client Server (HMS CS) evaluation software for the evaluation of the measurement results by the doctor.

The blood pressure measurements can be read with the help of the HMS CS evaluation unit. Using the software, stored measurement results are automatically transferred to a PC, displayed on the screen as graphics, lists and statistics, and printed out.

The Mobil-O-Graph® can be prepared for the next patient immediately afterwards. This procedure can be completed in just a few minutes with little practice. This allows the doctor to use the device every working day around the clock.

The Mobil-O-Graph® with the HMS CS is designed to allow documentation and visualisation of a blood pressure profile throughout the day and night. Additional parameters such as night-time values and blood pressure fluctuations are detected. This allows the doctor to prescribe individual and optimal medical treatment and monitor its outcome.

Please refer to the HMS CS instructions for use for software operating instructions.

## 3.2 Unpacking

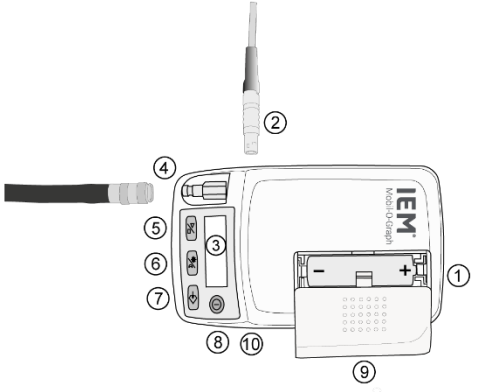
All parts included in the scope of delivery have been properly packed and checked for completeness and functionality. Should the product be incomplete or damaged, please inform the supplier immediately.



## 3.3 Description of device

### 3.3.1 Blood pressure monitor

Components:




1. Battery compartment
2. Data socket for PC interface cable
3. LCD Display
4. Cuff connection
5. START button
6. DAY/NIGHT button
7. EVENT button
8. ON/OFF button
9. Battery compartment lid
10. Infrared interface
11. Bluetooth®-interface (not visible)

Fig. 1: Blood pressure monitor, view from above

### 3.3.2 Buttons

All buttons are located in the housing top of the blood pressure monitor (see Fig. 1)).

**ON/OFF**

The ON/OFF button turns the blood pressure monitor on and off. To avoid accidental switching on or off, the button only reacts after 2 seconds.

You can also prematurely terminate the measuring process with this button, as well as with any other button: the pressure in the cuff is then quickly released (also see the section on warnings).

**Note**

- Switch the device on again to continue working.
- When the internal memory battery is empty and the external batteries are replaced, the device starts up in the last used operating state without the ON/OFF button being pressed.

**DAY/NIGHT**

The awake and sleep phases can be separated during recording with the DAY/NIGHT button, which is important for statistics and graphic representations. The detailed specification regarding the implications for the printout can be found in the respective chapters for the evaluation units.

The detailed specification regarding the implications for the printout can be found in the HMS CS instructions for use.

**In short**: The patient is instructed to press the DAY/NIGHT button when going to bed and again when getting up in the morning. This individually adapts the measurement interval to the patient and assists you in the analysis of the blood pressure profile. Next to the interval adjustment, you will find corresponding notes on the printout. If this button is not pressed, the interval is changed according to the log set.

**EVENT**

The EVENT button can be used to trigger an additional measurement to record an event that affects blood pressure. The patient should record the circumstances of the event, such as taking medication, for example, in a personal measurement log so that he/she can discuss the events with you.

**WARNING**

After an automatic measurement, allow at least 3 minutes to elapse to avoid prolonged impairment of blood circulation before actively starting a measurement.

**START**

The START button is used to activate 24-hour measurement and to perform a measurement outside the predetermined measurement cycle.

**WARNING**

The values of the first measurement should be checked by the doctor for plausibility so that subsequent correct automatic measurements can be carried out and correct cuff positioning is ensured. In the event of an error measurement, please follow the instructions in chapters 3.4 “Preparation for measurement” and 5 “Troubleshooting”.

If the START button is pressed, the display shows the number of previously registered measurements and the manual measurement is started. It differs from the automatic measurement according to the measurement log by a gradual inflation of the cuff. Here, the required pressure of the cuff is determined at which the systolic blood pressure value can be measured. This maximum required inflation pressure is stored and is immediately "started up" by direct inflation during the subsequent automatic measurements.

The patient can use the START button to initiate manual measurements in addition to the predetermined measurement cycle.

### 3.3.3 The display

The LCD display is located on the housing top of the blood pressure monitor (see Fig. 1). It displays useful information for the doctor and the patient regarding measurement data, blood pressure monitor settings and measurement errors.

### 3.3.4 Audible signals

The audible signals used consist of individual or multiple burst sequences.

The following burst sequences are emitted:

| Tone burst | Heard when |
|---|---|
| 1 tone burst | ▪ Switching on and off<br>▪ Starting and ending measurement (except during the night-time interval)<br>▪ Removing the interface cable, ending IR communications, establishing and ending Bluetooth® communications<br>▪ Measurement errors |
| 3 tone bursts | ▪ System error (e.g. measurement terminated) |
| Continuous tone bursts | ▪ Serious system error (e.g. the cuff pressure is greater than 15 mmHg for more than 10 seconds outside the measurement) |
| Combined tone bursts | ▪ When manually clearing the readings, 1 tone burst is emitted first and 2 seconds later 5 tone bursts |

### 3.3.5 Cuff connection

The cuff connection is located on the housing top of the Mobil-O-Graph® (see Fig. 1). This metal plug is needed to connect the blood pressure monitor to the cuff via the cuff tube and the metal sleeve of the cuff.

**! ATTENTION**

The metal plug (air coupling) must always engage with an audible "click". Otherwise there will be a leaky connection between the Mobil-O-Graph® and tube which will lead to measurement errors.

### 3.3.6 Data socket

The data socket is located on the left side of the housing. The connection cable provided is connected to this socket. This is a plug connection; the red dot of the plug must be plugged onto the red dot of the socket. Pull the outer metal ring to release the connection.

Further information can be found in the HMS CS instructions for use.

### 3.3.7 Infrared interface

The infrared interface provides an equivalent wireless alternative to the data socket. To use this interface, you need the PC infrared interface IR-Med. The infrared interface can be acquired from your specialist supplier or directly from IEM GmbH.

Further information can be found in the HMS CS instructions for use.

## 3.4 Preparation for measurement

- Connect the tube of the cuff to the plug on the housing top of the blood pressure monitor.
- First of all, check that the rechargeable batteries are inserted correctly. You should always use fully charged rechargeable batteries for a new measurement. Alternatively, you can also use alkaline batteries. When inserting the power pack or batteries, please ensure correct polarity.

**Note**

Only use the IEM NiMH rechargeable batteries or alkaline batteries provided. Although zinc-carbon batteries and NiCd rechargeable batteries show sufficient voltage during the battery test, the power is often insufficient to take measurements for 24 hours. The rechargeable batteries should be discharged and recharged several times before their first use. Please observe the enclosed instructions for use for the charger.

### 3.4.1 Switching on

Always check the condition of your blood pressure monitor first before giving it to a patient. This is done by observing the first notifications on the display of the blood pressure monitor shortly after switching it on.

The following should be displayed in this sequence:

| Test | Display | Comment |
|---|---|---|
| Battery status (volts) | 2.85 | at least 2.6 V for NiMH rechargeable batteries<br>at least 3.10 V for alkaline batteries |
| Display Segment Test | 999:999<br>to<br>000:000 | First the digits (999:999 to 000:000), then all other symbols of the LCD appear in succession.<br>Check whether all segments are correctly and fully displayed (the complete program code is checked for correctness in the background). |
| Current 24-hour period | 21:45 | Between 00:00 and 23:59 |

If an error occurs during the internal test, the blood pressure monitor will show E004 on the display and an audible signal will sound. For safety reasons, the blood pressure monitor will be out of operation. Send the blood pressure monitor immediately to your specialist supplier or directly to IEM GmbH for repair.

### 3.4.2 Clearing the memory

The memory must be empty before every measurement, i.e. there must be no blood pressure data from the previous patient in the memory. If there are still values in there, these can be cleared using the delete function of the evaluation software.

You can clear the memory manually by holding down the start button for more than 5 seconds. As it is held down, all segments of the LCD will be displayed first of all, then 1 tone burst will be emitted, the number of saved measurements will be displayed briefly and then "clr" will be displayed. If the event button is now pressed for more than 2 seconds within 5 seconds, all measurements will be deleted.

### 3.4.3 Setting the time/date

The Mobil-O-Graph® has an internal backup battery which allows the time to continue even after removing the power pack or batteries from the battery compartment. Nevertheless, the time and the date should be checked before every measurement series.

The time and date can be set with the respective evaluation software.

You can set the time and date manually by holding down the start button and pressing the event button. Now you are in the "set time" mode. Use the start button to change each item and use the event button to jump to the next display item.

### 3.4.4 Transferring patient data (ID)

The blood pressure monitor must be prepared by transferring patient data (ID) with the help of the HMS CS so that correct data allocation is possible when reading out.

Further information about this can be found in the HMS CS instructions for use under "accepting patient ID".

### 3.4.5 Specifying the desired measurement log

You have the option, using the HMS CS, to adjust the following settings for the measurement log:

- Beginning of 4 different daily intervals
- Number of measurements per hour in the 4 daily intervals
- Enable/disable the acoustic signals for the daily intervals
- Enable/disable the optional PWA
- Choose between 24-hour ABPM and in-clinic monitoring
- Turn the display on/off.

As soon as you have conducted a measurement, the log can only be changed once you have completely deleted all data.

You can set the log manually by pressing and holding the day/night button while simultaneously pressing the event button. Use the start/stop button to change the log and confirm with the event button.

**Note:**

To use practice monitoring a Bluetooth® interface is required; you can obtain one of these via your specialist supplier or directly from IEM GmbH.

**Setting the logs via software**

To set the protocols using the software please refer to the HMS CS instructions for use for the respective patient data management software.

### 3.4.6 Putting on the blood pressure monitor and starting the measurement

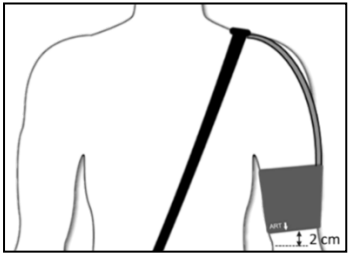



Fig. 2: Putting on the cuff

Place the monitor pouch on the patient. By varying the length of the strap, you can use it either as a waist strap or as a shoulder strap. Alternatively, a normal belt can be used that matches the clothes. Now put the cuff on the patient. Correct positioning of the cuff is important for accurate measurement (see Fig. 2).

We recommend placing the cuff on the bare upper arm. However, the cuff can also be worn over a thin shirt or a thin blouse.

**Please note the following:**

1. When connecting the monitor to the patient, the monitor must not be connected to other external devices!
2. The cuff must be positioned so that the pressure tube cannot be kinked at any point! Here, the course of the pressure tube should ensure free movement of the upper arm and should be guided around the neck to the other side of the body. In this regard, the tube connection on the cuff must face upwards.
3. It is imperative that the artery symbol be positioned on the brachial artery! When the cuff is put on correctly, the metal strap lies on the outside of the upper arm (elbow side).
4. The fabric strap must cover the skin underneath the metal strap!
5. The lower edge of the cuff should be about 2 cm (0,8 Inch) above the patient's elbow!

6. The cuff should only be placed on the upper arm. Correct positioning can be checked using a simple test: You should be able to insert one or two fingers under the cuff.
7. It is important for the cuff to be the correct size to ensure accurate blood pressure measurement. To make it possible to measure reproducible values, there should be standardised measurement conditions, i.e. the cuff size should be adjusted to the patient. The arm circumference can be measured with the tape measure included in the delivery package in the middle of the upper arm and the cuff is then selected:

| Upper arm circumference | Cuff |
|---|---|
| 14 - 20 cm (5,5-7,9 Inch) | XS |
| 20 - 24 cm (7,9-9,5 Inch) | S |
| 24 - 32 cm (9,5-12,6 Inch) | M |
| 32 - 38 cm (12,6-15,0 Inch) | L |
| 38 - 55 cm (15,0-21,7 Inch) | XL |

8. Connect the cuff pressure tube to the blood pressure monitor. Firmly attach the tube to the connector, the pressure tube must audibly click into place; when detaching, simply pull back the outer metal ring of the plug.
9. The blood pressure monitor is now properly set up and ready for measurement.

Instructions for preparing the blood pressure monitor using the HMS CS can be found in the HMS CS instructions for use.

After all the previous steps have been taken, the blood pressure monitor can be put into operation. First of all, a manual measurement is taken by pressing the "START" button. This measurement will make it possible to determine if the blood pressure monitor is working properly.

If errors occur, check that the monitor and accessories have been correctly set up and installed. If this does not help you, repeat the setup procedure.

**Only after a successful manual measurement can the patient be discharged until the patient returns for device removal.**

### Terminating measurement

During a measurement, the measurement can be terminated with **ANY** button. The display will then say "**-StoP-**" and a beep will sound 5 times. This termination will also be stored in the table of readings under “terminated”.

If the measurement is aborted, a new measurement will start after 3 minutes.

**Note**

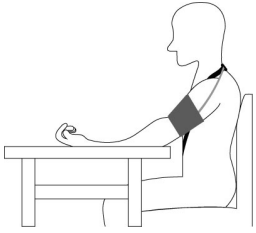
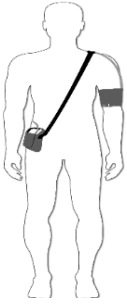
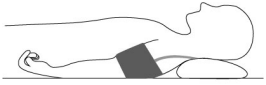
Before a 24-hour measurement, you should go through the patient information sheet with the patient. The information sheet is available at https://www.iem.de/en/patient-information/ .

## 3.5 Position and conduct of the patient

Show the patient how to put on the cuff so that it is at the level of the right atrium during the measurement.

Inform the patient that they should adopt one of the positions shown in Table 1 at the start of a blood pressure measurement if possible.

Tab. 1: Positioning during measurement

| 1st Position | 2nd Position | 3rd Position |
|---|---|---|
|  |  |  |

It is important here that the patient:

- is sitting/standing/lying comfortably
- does **not** cross their legs
- places their feet flat on the floor (when sitting or standing)
- supports their back and arms (when sitting or lying)
- keeps quiet and does **not** speak

**Note**

- The patient should relax as much as possible during the measurement and must not speak, unless this is to express discomfort.
- There must be 5 minutes' rest before the first reading is recorded.
- During a 24-hour measurement, the patient should adopt one of the three positions shown in Table 1 during a blood pressure measurement if possible.
- The measurements may be influenced by the measuring location, the position of the patient, the exertion or the physiological condition of the person to be measured.

## 3.6 Technical data and environmental conditions

| | |
|---|---|
| Measuring method: | Oscillometric measuring method |
| Measurement pressure range: | Systolic 60 to 290 mmHg<br>Diastolic 30 to 195 mmHg |
| Accuracy: | +/- 3 mmHg in display range |
| Static pressure range: | 0 to 300 mmHg |
| Pulse range: | 30 to 240 beats per minute |
| Procedure: | Oscillometric |
| Measurement intervals: | 0, 1, 2, 3, 4, 5, 6, 10, 12, 15, 20 or 30 measurements per hour |
| Measurement logs: | 4 changeable interval groups |
| Memory capacity: | 300 measurements (with PWA: 260 measurements) |
| Battery capacity: | > 300 measurements |
| Operating temperatures: | +10°C to +40°C |
| Operating humidity: | 15 % to 90 % rel. humidity |
| Storage environment: | -20°C to +50°C and 15 % to 95 % rel. humidity |
| Ambient pressure | 700 to 1060 hPa |
| Dimensions: | 128 x 75 x 30 mm |
| Weight: | approx. 240 g including batteries |
| Power supply: | 2 x Ni-MH rechargeable batteries, each 1.2 V and min. 1500mAh (AA, Mignon) 2 x 1.5 V alkaline batteries (AA, Mignon) |
| Interfaces: | IR-MED serial or USB (IEM specific)<br>PC combination cable USB or serial<br>Bluetooth® |

| | |
|---|---|
| Expected operational life of the device | 5 years |
| Expected operational life of the cuff | 6 months |

**Environmental conditions:**

**ATTENTION**

- Extremes of temperature, humidity or air pressure can affect measurement accuracy. Please observe the operating conditions.
- Extreme temperatures, humidity or altitude can affect the performance of the blood pressure monitor. Do not store the device near a fireplace or heating unit and do not expose it to intense sunlight. Do not place the device near a nebuliser or steam generator, as the condensation may damage it.

- The blood pressure monitor takes approx. 25 minutes to go from the minimum storage temperature of -20°C to the operating temperature of +10°C in an ambient temperature of +20°C.
- The blood pressure monitor takes approx. 25 minutes to go from the maximum storage temperature of +50°C to the operating temperature of +40°C in an ambient temperature of +20°C.

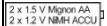
## 3.7 Symbols

**Note**

The symbols on the buttons are described in chapter 3.3.2 “Buttons”.

EN

Explanation of the label symbols:

| Symbol | Explanation |
|---|---|
|  | Comply with the instructions for use! |
|   | The battery symbol indicates the type of power supply. |
|  | FCC marking for communication devices |
|  | Manufacturer |
|  | Defibrillation-proof type BF applied part |
|  | The product is not to be treated as normal domestic waste, but should be taken to a recycling point for electric and electronic devices. Further information can be obtained from your local authority, municipal waste disposal companies or specialist dealers. |
|   | The device fulfils the essential requirements of Directive 93/42/EEC. |
|  | The device emits electromagnetic waves. |
|  | The product has a Bluetooth® interface. |

| Symbol | Explanation |
|---|---|
|  | Date of manufacture YYYY-MM-DD |
|  | MR unsafe: The product poses hazards in MRT environments |
|  | Serial number |
|  | Protection class |

# 4 Care and maintenance

Regular maintenance and care of your Mobil-O-Graph® is required in order to maintain the proper functioning of your Mobil-O-Graph® in the long term.



## 4.1 Disinfection and cleaning

The user (doctor) decides whether and when the cuff sleeve needs to be disinfected for hygienic reasons (e.g. after each use).

**Note**

Always observe the manufacturer's instructions on the disinfection and cleaning of these products.

**WARNING**

- When putting the device on, there must no longer be any disinfectant on the blood pressure cuff!
- There are patients who have intolerances (e.g. allergies) to disinfectants or their components!

**ATTENTION**

- Do not immerse the cuff with balloon or the blood pressure monitor in disinfectant, water or other liquids!
- If liquid gets into the device, switch it off immediately and send it to your specialist supplier or directly to IEM GmbH for inspection!
- Do not open the casing of the Mobil-O-Graph®, otherwise any warranty will no longer be valid!

## Disinfection:

IEM has tested the following means for the disinfection of the cuff sleeve:

- Promanum N (B. Braun)
- Terralin liquid (manufacturer: Schülke & Mayr)

When using other disinfectants that have not been tested by IEM, the burden of proof that these can be used without causing damage lies with the user. Never use disinfectants which leave residue on the product or which are not suitable for contact with the skin.

To achieve the optimum effect, apply the disinfectant to the cuff sleeve for at least 5 minutes.

Always allow the agents to dry without any residue.

Ensure that any disinfectants used are washed off, leaving no residue, before the blood pressure sleeve is worn.

Cleaning:

**ATTENTION**

- To clean, use lukewarm water up to 30°C max., to which you can add a mild detergent if necessary.
- Do not use fabric softeners or other additives (e.g. hygiene rinses, textile deodorants). These agents can leave behind residue and damage the material!
- The cuff sleeve can be washed in the washing machine up to 30°C using a mild detergent without spin-dry.
- The cuff sleeve is not suitable for drying in a dryer.

**Balloon**: Wipe the balloon with lukewarm water only, adding a mild detergent if necessary. Ensure that no water enters the tube opening.

**Blood pressure monitor**: Only clean the Mobil-O-Graph® with a damp cotton cloth. No harsh or solvent-based additives may be used. Ensure that no water enters the device!

**Pouch**: Please only clean the bag with a damp cotton cloth with water or a mild detergent (no harsh or solvent-based additives may be used).

## 4.2 Maintenance plan

Please check the battery/power pack voltage on a weekly basis.

For the battery/power pack voltage curve, please refer to the HMS CS instructions for use.

**Every 2 years:**

**As proof of continuous compliance to "Basic Requirements" pursuant to Directive 93/42/EEC, the Mobil-O-Graph® blood pressure monitor must undergo metrological checks every two years. In certain countries, this requirement may be regulated by national laws or regulations.**

In addition to re-calibration, IEM products do not require any services referring to low-voltage regulations and compatibility.

For details on re-calibration services, kindly contact your local IEM Distributor.

**Rechargeable batteries:**

Rechargeable batteries are liable to ageing. Rechargeable batteries that are damaged, or with which a 24-hour measurement is no longer possible, must be replaced immediately.

We recommend that you only use the rechargeable batteries supplied by IEM, the capacity and quality of which has been tested. It is important to make sure that the capacity of the rechargeable batteries is above 1500 mAh.

For further information, please refer to the instructions for use of the charger

# 5 Troubleshooting

**Note**

In case of an error message, the device starts a new measurement after 3 minutes, except for the activation measurement.



## 5.1 Main sources of error

The following can cause error measurements or unwanted results:

- The patient’s arm moving during measurement
- Device being switched off (e.g. at night)
- Incorrect cuff size put on
- The cuff slipping while being worn
- Lack of successful manual measurement in the doctor's practice
- Not taking the medication
- Incorrect log set
- Not fully charged, incorrectly charged or outdated rechargeable batteries used
- Kinking or knotting of the cuff tube
- External interference factors such as, for example, physical activity or driving or using public transport during measurement may result in so-called motion artefacts or incorrect measurements.

## 5.2 Transmission error

To avoid an error during data transmission, the blood pressure monitor includes a check of the data sent. If an error has occurred, E004 will appear on the display.

## 5.3 Checklist

Please go through the following checklist if you have encountered errors when handling the Mobil-O-Graph®. Many errors have simple causes.

- Check that all cables are firmly connected and/or that the infrared interface is correctly aligned with the device.
- Check if the blood pressure monitor, computer and printer are switched on (depending on the version you have received).
- Check that the connection cable is connected to the correct serial interface (COM1 to COM4).
- Check that the rechargeable batteries are sufficiently charged.

**Note**

Some errors are combined with a continuous alarm for safety reasons. The continuous alarm can be ended by pressing any button. If there is residual pressure inside the cuff, open the cuff immediately.

## 5.4 Mobil-O-Graph® error description

| Error message | Possible cause | Measures |
|---|---|---|
| Err 1 | 1. The patient has severe arrhythmia | 1. Blood pressure monitor not applicable |
| | 2. Arm moved during measurement | 2. Keep the arm still during measurement |
| | 3. Insufficient valid pulse rate detected | 3. Place the cuff on the arm again |
| Err 2 | 1. Arm moved during measurement | 1. Keep the arm still during measurement |
| | 2. Cuff does not fit the arm snugly | 2. Check the seating of the cuff and that of the device |
| Err 3 | 1. Blood pressure is beyond the measurement range | 1. Permanent notifications render the blood pressure monitor unsuitable for the patient. |
| | 2. Considerable arm movement | 2. Keep the arm still during measurement. |
| | 3. Problems with the pneumatics | 3. If this error occurs continuously, send the device to your specialist supplier or directly to IEM GmbH for checking. |

| Error message | Possible cause | Measures |
|---|---|---|
| Err 4 | 1. Data transmission cable not correctly inserted into the blood pressure monitor | 1. Insert the cable correctly into the blood pressure monitor (see chapter 3.4 “Preparation for measurement”). |
| | 2. Pins in the plug of the data transmission cable are mechanically damaged. | 2. Check the plug to see whether the pins on the inside are damaged. If they are, call your specialist supplier or IEM GmbH. |
| | 3. Reading not transmitted correctly | 3. Start the transmission again. |
| Err 5<br>bAtt | 1. Power pack or battery voltage too low | 1. Replace the rechargeable batteries or batteries |
| | 2. Rechargeable batteries or batteries defective | 2. The power pack or battery voltage is correct but **bAtt** is shown on the display during cuff inflation. Replace the rechargeable batteries |
| | 3. Battery contacts are corroded | 3. Clean the battery contacts with a cotton cloth and a little alcohol. |

| Error message | Possible cause | Measures |
|---|---|---|
| Err 6<br>+<br>possible continuous alarm until a button is pressed | 1. Build-up of air | 1. Check the cuff for a build-up of air or a kink in the tube. If there is a kink in the cuff tube, lay the tube out. Otherwise, send the device in immediately. |
| | 2. Blood pressure cuff incorrectly connected | 2. Connect the cuff to the device (see chapter 3.3.5 “Cuff connection”) |
| | 3. Leak in the cuff or connecting tube | 3. If necessary, replace the cuff or connecting tube. |
| Err 7 | The memory of the blood pressure measuring device is full (a maximum of 300 measurements and events can be stored or in the case of PWA a maximum of 260) | Delete the data in the blood pressure monitor but make sure that the data has been saved (see chapter 3.4.2 “Clearing the memory”). |
| Err 8 | Measurement cancelled by pressing a button | Repeat the measurement |

| Error message | Possible cause | Measures |
|---|---|---|
| Err 9<br>+<br>possible continuous alarm until a button is pressed | 1. Residual pressure inside the cuff | 1. Wait for the cuff to deflate completely. |
| | 2. Zero point comparison could not be performed successfully. | 2. Send the device immediately to your specialist supplier or directly to IEM GmbH for checking. |
| Err 10<br>+<br>Continuous alarm until a button is pressed | 1. Serious error due to pressure build-up outside the measuring process (pump has been switched on against orders) | Send the device immediately to your specialist supplier or directly to IEM GmbH for checking and repairs. |
| | 2. These error messages all show a severe error in the program code. | |

| Error message | Possible cause | Measures |
|---|---|---|
| The evaluation unit is not reacting to data transfer but **co** is shown on the display. | 1. Data transmission cable has not been inserted properly into the PC. | 1. Check whether the 9-pin plug of the data transmission cable is securely located in the device's interface socket. |
| | 2. Also see Err 4 | 2. Also see Err 4 |
| The desired log cannot be set with the button combination. | There are still readings from the last patient in the memory | Delete the data in the blood pressure monitor but make sure that the data has been saved (see chapter 3.4.2 "Clearing the memory") |
| The blood pressure monitor cannot be switched on. | 1. The rechargeable batteries or batteries have been incorrectly inserted | 1. Reinsert both rechargeable batteries or batteries and ensure correct polarity. |
| | 2. The power pack or battery voltage is too low | 2. Replace the rechargeable batteries or batteries |
| | 3. The display is faulty | 3. Send the device to your specialist supplier or directly to IEM GmbH for repair. |
| An error occurs during the first measurement. | The cuff size does not fit the patient's arm circumference. | Check the circumference of the arm using the tape measure provided and compare it to the information printed on the cuff. |

### 5.4.1 Communication error Mobil-O-Graph® Bluetooth® interface

| Error indication | Possible cause | Remedy |
|---|---|---|
| cod 1 | Bluetooth® interface of the Mobil-O-Graph® did not start up correctly.<br>Possible hardware fault. | Send the device to your specialist supplier or directly to IEM GmbH for checking. |
| cod 2 | The Bluetooth® interface of the Mobil-O-Graph® could not be configured correctly.<br>(Communication problem between the Mobil-O-Graph® and Bluetooth® module.) | Try it again.<br>If the error persists, send the device to your specialist supplier or directly to IEM GmbH for checking. |
| cod 3 | The status of the Bluetooth® interface of the Mobil-O-Graph® could not be determined.<br>(Communication problem between the Mobil-O-Graph® and Bluetooth® module.) | Try it again.<br>If the error persists, send the device to your specialist supplier or directly to IEM GmbH for checking. |
| cod 4 | The Bluetooth® interface of the Mobil-O-Graph® is not yet connected to the Bluetooth® dongle. | Try connecting to the device<br>via Bluetooth® again. |
| cod 5 | The Bluetooth® interface of the Mobil-O-Graph® could not connect to the Bluetooth® dongle on the computer. | Try it again.<br>If the error persists, send the device to your specialist supplier or directly to IEM GmbH for checking. |

| Error indication | Possible cause | Remedy |
|---|---|---|
| cod 6 | The measurement value memory of the Mobil-O-Graph® does contain any blood pressure values that have not yet been sent. | After taking further measurements, these are sent. |
| cod 7 | The Mobil-O-Graph® is connected to a mobile phone or GSM modem which is technically incapable of sending readings, is outside the network range or is not configured correctly. | Try it again.<br>If the error persists, please contact your specialist supplier or IEM GmbH. |

# 6 Rechargeable batteries/batteries

## 6.1 Operation with rechargeable batteries

IEM supplies high-quality "ready to use" NiMH rechargeable batteries with at least 1500 mAh which have very low self-discharge. We recommend that you only use these rechargeable batteries!

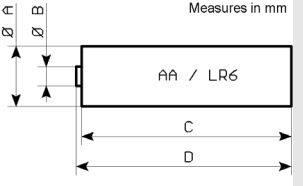
**WARNING**

- Do not use rechargeable batteries that have been stored above 45°C or below 0°C.
- If the operating time of the rechargeable batteries drops significantly, replace all rechargeable batteries at the same time. Never use old used rechargeable batteries together with new unused rechargeable batteries!

**ATTENTION**

**Dimensions of permissible rechargeable batteries and batteries**

Only use rechargeable batteries or batteries or batteries with the following dimensions:




| | MIN | TYP | MAX |
|---|---|---|---|
| A | | 14,00 | 15,00 |
| B | | 5,00 | 5,50 |
| C | | | 48,75 |
| D | 49,50 | | 50,50 |

Tips:

- Fully charge the rechargeable batteries before using them for the first time.
- Please note that NiMH rechargeable batteries only reach their full charge capacity after the 4th charging cycle.
- Recharge rechargeable batteries again if they have been lying around unused for a long time.
- Avoid total discharge in order to protect your rechargeable batteries.

**Note**

Only use the rechargeable batteries supplied by us with the charger.

**ATTENTION**

Never charge non-rechargeable batteries. These can leak or explode and cause damage to your health.

For further information, please refer to the instructions for use of the charger.

## 6.2 Operating with ALKALINE batteries

The Mobil-O-Graph® can also be operated with alkaline manganese batteries. These batteries are non-rechargeable and therefore must not be placed into the charger.

Two alkaline batteries have a higher charging voltage when full (at least 3.1 V) than 2 NiMH rechargeable batteries (at least 2.6 V). The battery indicator in the recorder will therefore also display a higher voltage.

Insert these batteries into the battery compartment in the same way as the rechargeable batteries (pay attention to polarity). After the 24-hour measurement cycle, remove the batteries and dispose of them.

Remember that batteries are hazardous waste and must therefore be disposed of separately.

# 7 Warranty and repair conditions



**Warranty:**

IEM GmbH provides a two-year warranty on the hardware, i.e. the blood pressure monitor itself. The warranty is no longer valid if the device has been opened, misused or negligently or intentionally damaged. Likewise, the warranty is no longer valid if the device has been repaired by an unauthorised body. Only the NiMH rechargeable batteries can be replaced by the operator.

The normal wear and tear of rechargeable batteries, transmission cables or cuffs including tube cannot be claimed under the warranty. In the scope of the warranty, IEM is only responsible for defects that already existed when the product was handed over to the customer (and possibly only showed up later).

Furthermore, the warranty does not apply if the defect is due to violation of the instructions for use, improper handling, moisture, humidity or extreme heat or climate conditions or short-term fluctuations in corresponding influences or is due to corrosion, oxidation, unauthorised intervention or connection attempts, unauthorised opening or repair, attempts at repair with non-approved replacement parts, incorrect operation, improper installation, accidents, forces of nature, spillage of food or drink, chemical effects or other external influences which IEM cannot influence (among other things, defects in consumables such as batteries and rechargeable batteries, for example, which inevitably only have a limited operating life, are excluded), unless the defect is directly due to a material defect, design fault or manufacturing error.

**Repairs:** If the device malfunctions or if you experience continuous measurement errors, contact your Mobil-O-Graph® specialist supplier or IEM GmbH directly for repairs and shipping instructions.

> **!** ATTENTION
>
> **Do not open the housing.**
> - Once the device has been opened, any warranty will no longer be valid.

**Metrological checks:** **As proof of continuous compliance to "Basic Requirements" pursuant to Directive 93/42/EEC, the Mobil-O-Graph® blood pressure monitor must undergo metrological checks every two years. In certain countries, this requirement may be regulated by national laws or regulations.**

**Liability clause**: In all cases where IEM is obliged to pay damages or reimburse expenses on the basis of contractual or statutory claims, IEM is liable only to the extent that its executives and vicarious agents are guilty of intent or gross negligence. Strict liability according to the Product Liability Act remains unaffected. Liability for the culpable breach of essential contractual obligations also remains unaffected, however, except in the cases of clauses 1 and 2, liability is limited to foreseeable damage which is typical for this type of contract.

A change in the burden of proof to the disadvantage of the customer is not connected with the above regulations. Liability for quality or durability guarantees or fraudulent concealment of defects is not affected by the provisions outlined above.

# Appendix

## Appendix 1 Important patient information



This patient information can also be found in DIN A4 format at:
https://www.iem.de/en/patient-information/
If necessary, you can print it out and give it to the patient.

### Patient information sheet

This patient information sheet gives you important safety information about using the **Mobil-O-Graph®** for 24-hour long-term blood pressure measurement. For ease of reading, only the name Mobil-O-Graph® is used in this information sheet as the description applies to both models. Read the information sheet about the long-term blood pressure measuring device carefully before use! It is **important** that you understand the information. If you have any questions, please contact your doctor.

### Patient safety instructions

**WARNING**

- Only use the accessories given to you by your doctor!
- Do not put the cuff tube or the shoulder strap around the neck as there is a risk of strangulation!
- Always put the cuff tube under clothing (even at night).
- Measurement can be interrupted at any stage by pressing any button. This deflates the cuff and the device can be removed.
- Do not kink the cuff tube and avoid too frequent measurements, otherwise circulation problems could result.

- Turn off the device, remove the cuff and inform the doctor if you experience any pain, swelling, redness or numbness in the arm around which the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)
- Ensure the correct positioning of the shoulder strap/waist belt and cuff tube, also see Fig. 1.
- External interference factors such as, for example, movement of the arm being measured, physical activity or driving or using public transport during measurement may result in so-called motion artefacts or incorrect measurements. Keep a personal measurement log so that the doctor carrying out the evaluation can include this in the assessment.
- Switch off the device immediately and remove the cuff and the device if you experience an allergic reaction on the arm of the blood pressure measurement.
- Self-diagnosis and self-treatment on the basis of the results is dangerous. Do not undergo any treatment (or change of treatment) without consulting your doctor.

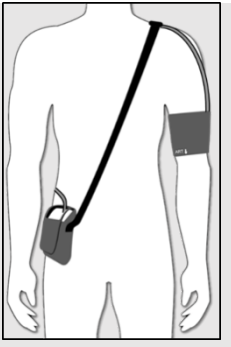


Fig 1: Mobil-O-Graph® with shoulder strap

- Make sure that the pressure tube of the cuff cannot be kinked or squeezed, especially when sleeping.
- Bleeding in the skin or muscles may occur in patients with sensitive body tissue (petechiae, haemorrhages or subcutaneous haematomas).
- Do not place the Mobil-O-Graph® over a wound or bandage.
- If the patient has limited cognitive abilities, the device may only be used under supervision.

**! ATTENTION**

- Do not open the casing. Once the device has been opened, any warranty will no longer be valid.
- Liquid must not get into the device. If you want to have a shower or bath, switch off the device and take it off. Make sure that you put it back on properly afterwards and switch it on! If you think that liquid has entered the device, the device must not be used. Switch the device off and remove the batteries.
- Do not wear any other electrical medical devices on the arm you are using to measure your blood pressure and do not use the device in the vicinity of an MRI scanner.
- The device must not be used on aeroplanes.
- The Mobil-O-Graph® fulfils all requirements of the EMC standards, but it should not be exposed to strong electromagnetic fields as this may cause malfunction outside the limits. You should therefore ensure that the Mobil-O-Graph® is at least 30 cm (12 inches) from any portable RF communication devices.

## Taking off the cuff and blood pressure measuring device

If you need to remove the cuff and the device (e.g. to have a shower), proceed as follows:

- Switch the device off using the ON/OFF button.
- Remove the cuff from the arm.
- Take the device and the shoulder strap off.

## Putting on the cuff and blood pressure measuring device

The correct positioning of the arm cuff is very important for an accurate measurement and should always be done on the same arm.

To put the cuff and blood pressure measuring device on again, follow these instructions:

- The tube connection on the cuff must face upwards, see Fig. 1.
- The course of the cuff tube should ensure free movement of the upper arm and should be guided around the neck to the other side of the body.
- Align the cuff so that no part of the cuff tube can be kinked. Align the cuff so that the lower edge of the cuff is about 2 cm (0,8 Inch) above your elbow, see Fig. 2.
- Place the cuff around the upper arm in such a way that one finger can be inserted underneath the cuff.
- Make sure that the artery symbol on the cuff is positioned on the arm artery (brachial artery), see Fig. 2.
- When the cuff is put on correctly, the metal strap lies on the outside of the upper arm (on the elbow side). Here, the fabric strap must cover the skin underneath the metal strap.
- We recommend placing the cuff on the bare upper arm. However, the cuff can also be worn over a thin shirt or a blouse.
- Put the holster on. By varying the length of the strap, you can use it either as a waist strap or as a shoulder strap.

- Insert the Mobil-O-Graph® into the holster so that the cuff connection and the buttons are freely accessible for operation.
- Switch the Mobil-O-Graph® on using the **ON/OFF** button.
- Start a new blood pressure measurement by pressing the **START** button.

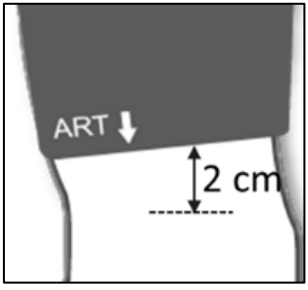
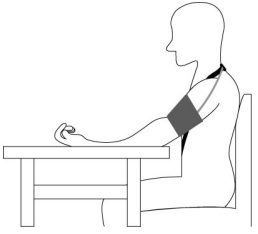
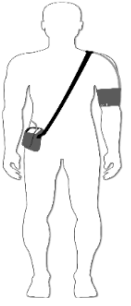
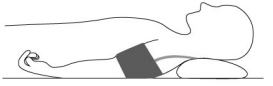



Fig. 2: Positioning of the cuffs

## Conduct during a measurement

Make sure that the middle of the cuff is located at the level of your right atrium. When a blood pressure measurement starts, adopt one of the following positions if possible:

| 1st Position | 2nd Position | 3rd Position |
|---|---|---|
|  |  |  |

- Sitting/standing/lying comfortably
- **Not** crossing your legs
- Keeping quiet and **not** speaking
- Feet flat on the floor (when sitting or standing)
- Supporting the back and arms (when sitting or lying)

## Buttons of the Mobil-O-Graph®

The Mobil-O-Graph® has 4 buttons which can be used to perform various functions:

**ON/OFF** button

You can turn the Mobil-O-Graph® on and off using the **ON/OFF** button. To avoid accidental switching on or off, the button must be held down for at least 2 seconds.

You can also prematurely terminate the measuring process with this button, as well as with any other button. The pressure in the cuff is then quickly released.

**START** button

The **START** button is used to start the automatic log and triggers an additional manual measurement. In addition, pressing the **START** button will allow you to continue the measurement cycle if you have terminated a blood pressure measurement by pressing any button, or if you have switched the Mobil-O-Graph® off and back on again. The button can also trigger an additional single measurement; however, this should only be done after consultation with the doctor. Special events are recorded using the **EVENT** button, see **EVENT** button.

**DAY/NIGHT** button

Press the **DAY/NIGHT** button in the evening before going to bed and again in the morning when you get up. Pressing the **DAY/NIGHT** button is stored together with the measurement results and allows your doctor to carry out a more detailed evaluation.

**EVENT** button

Press the **EVENT** button to record an event which may affect the blood pressure and to trigger an additional measurement. Pressing the **EVENT** button is stored together with your measurement results and allows your doctor to carry out a more detailed evaluation. Make a note of the circumstances of the event in a personal measurement log so that you can discuss the events

with your doctor afterwards. Special events are, for example, taking medication, chest pains, shortness of breath or similar.

**WARNING**

After an automatic measurement, allow at least 3 minutes to elapse to avoid prolonged impairment of blood circulation before actively starting a measurement.

## Audible signals

The audible signals generated by the device consist of individual or multiple tone burst sequences. The following tone burst sequences are emitted:

| Tone burst | Heard when |
|---|---|
| 1 tone burst | ▪ Switching on and off<br>▪ Starting and ending measurement (except during the night-time interval)<br>▪ Removing the interface cable, ending IR communications, establishing and ending Bluetooth® communications<br>▪ Measurement errors |
| 3 tone bursts | ▪ System error |
| Continuous tone bursts | ▪ Serious system error (e.g. the cuff pressure is greater than 15 mmHg for more than 10 seconds outside the measurement) |

## Troubleshooting

In the event of measurement or system errors, an error code will appear on the display of the Mobil-O-Graph® for a few seconds. The following support instructions will help you understand how to deal with each error code:

| Error code | Measures |
|---|---|
| ERR 1 | Keep your arm still during the measurement. If the error recurs, refit the cuff. If the error appears continuously, please contact your doctor. |
| ERR 2 | Keep your arm still during measurement. If the error occurs repeatedly, check the positioning of the arm cuff and check that the cuff tube is firmly connected to the Mobil-O-Graph®. |
| ERR 3 | Keep your arm still during measurement. If this error persists, please contact your doctor. |
| ERR 5 | The batteries of the Mobil-O-Graph® are empty. Please contact your doctor. |
| ERR 6 | Check whether the cuff tube is kinked. If the error persists, please contact your doctor. |
| ERR 7 | Measurement storage is full. Please contact your doctor. |
| ERR 8 | The measurement was terminated by pressing a button. Repeat the measurement. Press the START button. |
| ERR 9 | Please contact your doctor. |
| ERR 10 | Please contact your doctor. |

## Appendix 2 EMC Guidelines and Manufacturer's Declaration

| Guidelines and Manufacturer's Declaration – electromagnetic emissions | | |
|---|---|---|
| The blood pressure measuring device Mobil-O-Graph® is intended for use in the environment specified below. The customer or user of the blood pressure measuring device Mobil-O-Graph® should ensure that it is used in such an environment. | | |
| Emitted interference measurement | Compliance | Electromagnetic environment – guidelines |
| RF interference emissions according to CISPR 11 | Group 1 | The blood pressure measuring device Mobil-O-Graph® only uses RF power for its internal functioning. Its RF emission is therefore very low and it is unlikely that any neighboring electronic device will experience any interference. |
| RF interference emissions according to CISPR 11 | Class B | The blood pressure measuring device Mobil-O-Graph® is suitable for use in facilities other than residential areas and those directly connected to a public supply network, which also supplies buildings used for residential purposes. |
| RF interference emissions according to CISPR 25 | Not applicable | |
| Harmonic oscillations according to IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flickers according to IEC 61000-3-3 | Not applicable | |

| Guidelines and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The blood pressure measuring device Mobil-O-Graph® is intended for use in the environment specified below. The customer or user of the blood pressure measuring device Mobil-O-Graph® should ensure that it is used in such an environment. | | | |
| Immunity test | Test level | Compliance level | Electromagnetic environment – guidelines |
| Electrostatic discharge (ESD) according to IEC 61000-4-2 | +- 8 kV contact discharge<br>+- 15 kV air discharge | +- 8 kV contact discharge<br>+- 15 kV air discharge | Floors should consist of wood or cement or be covered with ceramic tiles. If the floor consists of synthetic materials, relative humidity must be at least 30 %. |
| Fast transient electrical disturbance/bursts according to IEC 61000-4-4 | ± 1 kV<br>100 kHz repetition rate | ± 1 kV<br>100 kHz repetition rate | |
| Surge voltages (surges) according to IEC 61000-4-5 | | Not applicable | The Mobil-O-Graph® does not have an AC power supply |

| Immunity test | Test level | Compliance level | Electromagnetic environment – guidelines |
|---|---|---|---|
| Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8 | 30 A/m | 30 A/m | Magnetic fields at mains frequency should match the typical values found in business or hospital environments. |
| Voltage dips, short interruptions and fluctuations in supply voltage according to IEC 61000-4-11 | | Not applicable | The Mobil-O-Graph® does not have an AC power supply |

| Guidelines and manufacturer's declaration – electromagnetic immunity | | |
|---|---|---|
| The blood pressure measuring device Mobil-O-Graph® is intended for use in the environment specified below. The customer or user of the blood pressure measuring device Mobil-O-Graph® should ensure that it is used in such an environment. | | |
| Immunity test | Test level | Compliance level |
| Radiated RF disturbance according to IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.7 GHz | 10 V/m |
| Conducted disturbances according to IEC 61000-4-6 | | Not applicable |

| Guidelines and manufacturer's declaration – electromagnetic immunity | | |
|---|---|---|
| The Mobil-O-Graph® is intended for use in the electromagnetic environment specified below. The customer or Mobil-O-Graph® user should ensure that is used only in such an environment. | | |
| Measurement of interference emissions | Test level | Compliance level |
| Radiated RF disturbance according to IEC 61000-4-3 | 380 - 390 MHz<br>27 V/m; PM 50%; 18 Hz | 380 - 390 MHz<br>27 V/m; PM 50%; 18 Hz |
| | 430 - 470 MHz<br>28 V/m; (FM ±5 kHz, 1 kHz sine)<br>PM; 18 Hz | 430 - 470 MHz<br>28 V/m; (FM ±5 kHz, 1 kHz sine)<br>PM; 18 Hz |
| | 704 - 787 MHz<br>9 V/m; PM 50%; 217 Hz | 704 - 787 MHz<br>9 V/m; PM 50%; 217 Hz |
| | 800 - 960 MHz<br>28 V/m; PM 50%; 18 Hz | 800 - 960 MHz<br>28 V/m; PM 50%; 18 Hz |
| | 1700 - 1990 MHz<br>28 V/m; PM 50%; 217 Hz | 1700 - 1990 MHz<br>28 V/m; PM 50%; 217 Hz |
| | 2400 - 2570 MHz<br>28 V/m; PM 50%; 217 Hz | 2400 - 2570 MHz<br>28 V/m; PM 50%; 217 Hz |
| | 5100 - 5800 MHz<br>9 V/m; PM 50%; 217 Hz | 5100 - 5800 MHz<br>9 V/m; PM 50%; 217 Hz |