

MOBIL O GRAPH[®]

Mobil-O-Graph[®] PWA
Mobil-O-Graph[®] NG

Operating manual EN



IEM[®]

Mobil-O-Graph® NG
Mobil-O-Graph® PWA
Long-term blood pressure measuring device
Ambulatory Blood Pressure Monitor



Evaluation unit:
Hypertension Management Software CS (HMS CS)



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1 Introduction

1.1 Preliminary note

Thank you for choosing a Mobil-O-Graph® New Generation (NG) or 24-hour pulse wave analysis monitor (PWA) long-term blood pressure measuring device. Both blood pressure measuring devices have been specially developed for 24-hour measurement and work according to the oscillometric measuring principle. As an additional feature, the Mobil-O-Graph® PWA allows you to perform a 24-hour pulse wave analysis. For ease of reading, the name Mobil-O-Graph® is used in this operating manual when the description applies to both models.

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 this operating manual

This operating manual will ensure that you become familiar with the long-term blood pressure measuring device and the accessories quickly and easily. 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 operating manual for software operating instructions.

This operating manual explains 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 familiarised with the blood pressure monitor on a step-by-step basis.

The operating manual should be kept for future use and must always be available to the user!

1.3 Clinical trials

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

1.4 CE Mark



The Mobil-O-Graph® NG and PWA fulfil the requirements of the

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

and bear 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: www.iem.de.

2 Directions for use

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® 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 aeroplanes!

Note

The Mobil-O-Graph® has not been tested for use on pregnant women or those suffering from preeclampsia.

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, EN 1060-3
- 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.

Basic safety means that the patient cannot be endangered by automatic operation of the device.

In the event of an unclear status or state of the device, the device must enter the secure standby mode by the device releasing the air in 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 in the area of domestic health care and professional facilities, such as first aid facilities and clinics. 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,
- suffer from myocardial hypertrophy
- or
- suffer from nephrological dysfunction
- require antihypertensive therapy.

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 this operating manual. 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 this operating manual:



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 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

Directions for use

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 operating instructions.
- 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/power packs. 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 www.iem.de. If necessary, you can print it out and give it to the patient.

3 Product description

3.1 Description

The outpatient blood pressure measuring system consists of two main components:

- the Mobil-O-Graph® NG or the Mobil-O-Graph® PWA 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 monitor can be read with the help of the HMS CS evaluation unit. Using the software, stored measurement results can be input into 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 operating manual for software operating instructions.

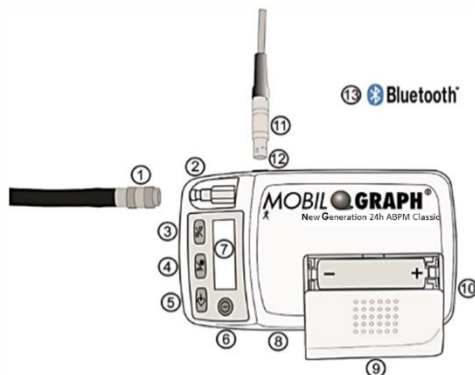
3.2 Unpacking

All parts included in the delivery package 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. Cuff tube
2. Cuff connection
3. START button
4. DAY/NIGHT button
5. EVENT button
6. ON/OFF button
7. LCD Display
8. Infrared interface
9. Battery compartment lid
10. Battery compartment
11. PC interface cable
12. Data socket
13. Bluetooth interface (not visible)

Fig. 1: Blood pressure monitor, view from above

3.3.2 Buttons

All buttons are located in the front casing 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 operating manual.

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 front casing 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	<ul style="list-style-type: none">▪ Switching on and off▪ Starting and ending measurement (except during the night-time interval)▪ Removing the interface cable, ending IR communications, establishing and ending Bluetooth communications▪ Measurement errors
3 tone bursts	<ul style="list-style-type: none">▪ System error (e.g. measurement terminated)
Continuous tone bursts	<ul style="list-style-type: none">▪ Serious system error (e.g. the cuff pressure is greater than 15 mmHg for more than 10 seconds outside the measurement)
Combined tone bursts	<ul style="list-style-type: none">▪ 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 front casing 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 casing (see Fig. 1). 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 operating manual.

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 obtained from your specialist supplier.



Further information can be found in the HMS CS operating manual.

3.4 Preparation for measurement

- Connect the tube extension to one of the cuffs provided by putting it on the plastic connector.
- Connect the tube of the cuff to the plug on the front casing of the blood pressure monitor.
- First of all, check that the power packs are inserted correctly. You should always use fully charged power packs 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 power packs or alkaline batteries provided. Although zinc-carbon batteries and NiCd power packs show sufficient voltage during the battery test, the power is often insufficient to take measurements for 24 hours. The power packs should be discharged and recharged several times before their first use. Please observe the enclosed operating instructions 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 power packs at least 3.10 V for alkaline batteries
Display Segment Test	999:999 to 000:000	First the digits (999:999 to 000:000), then all other symbols of the LCD appear in succession. 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 operating manual under "accepting patient ID".

3.4.5 Specifying the desired measurement log

You can choose between eleven (1-11) logs.

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.

Log table

Log	Interval	Time	Measurements per hour	Audible signal (buzzer)	Display of readings on the display	Adjustability
1	Day	08:00 - 23:59	4	YES	YES	YES
	Night	00:00 - 07:59	2	NO		
2	Day	08:00 - 22:59	4	YES	YES	YES
	Night	23:00 - 07:59	1	NO		
3	Day	07:00 - 21:59	4	YES	NO	NO
	Night	22:00 - 06:59	2	NO		
4	Day	08:00 - 23:59	4	YES	NO	NO
	Night	00:00 - 07:59	2	NO		
5	Day	18:00 - 09:59	4	YES	YES	NO
	Night	10:00 - 17:59	2	NO		
6	Day	07:00 - 23:59	4	YES	YES	NO
	Night	00:00 - 06:59	2	NO		
7	Day	06:00 - 22:59	4	YES	NO	NO
	Night	23:00 - 05:59	2	NO		
8	Day 1	07:00 - 08:59	6	YES	YES	NO
	Day 2	09:00 - 23:59	4	NO		
	Night	00:00 - 06:59	2	NO		
9	-	-	30	YES	YES	NO
10	Day	08:00 - 07:59	30	YES	YES	YES
	Night					
11	Day	08:00 - 23:59	4	YES	YES	YES
	Night	00:00 - 07:59	2	NO		

Setting the logs via software



To set the logs using software please refer to the HMS CS operating manual for the respective piece of patient data management software.

Note:

- Logs 1, 2, 10 and 11 can be changed via the HMS CS evaluation software. The changeable parameters are:
 1. Display of readings on the display
 2. Start of the 4 day intervals and the number of measurements per hour. The following are available: 4,5,6,10,12,15,20,30 per hour
 3. Turning on and off function of the buzzer for the 4 day intervals
- Logs 3 to 9 are pre-set and cannot be modified.
- Log 5 is suitable for activities during the night (night shift).
- Log 9 is the Schellong test. Here, the blood pressure is measured every 2 minutes during the first 30 minutes. After 30 minutes, the Mobil-O-Graph® takes measurements with log setting 3.
- Log 10 enables the automatic transmission of readings via Bluetooth® directly to the doctor's PC for actual measurements. To activate the Bluetooth® button you need a Bluetooth interface. In addition to blood pressure measurement, log 10 allows you to integrate pulse wave analysis with the Mobil-O-Graph® PWA.
- Log 11 is used for 24-hour pulse wave analysis, and can only be implemented with the Mobil-O-Graph® PWA. The measuring intervals are set via the HMS CS.

3.4.6 Putting on the blood pressure monitor and starting measurement

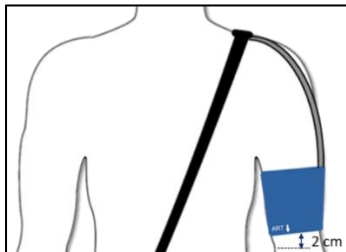


Fig. 2 Putting on the cuff

Place the holster 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.

Product description

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 operating manual.

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 you encounter any errors, check the correct procedure for setting up and putting on the equipment again. If this does not help you, repeat the setup procedure.

Only after a successful manual measurement can the patient be discharged until the device is removed.

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 www.iem.de.

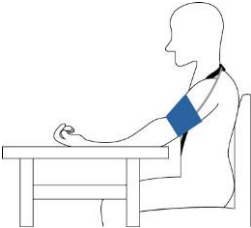

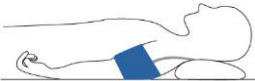
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3.5 Position and conduct of the patient

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.

Table 1: Positioning during measurement

1st Position	2nd Position	3rd Position
		

Product description

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

Measuring method:	Oscillometric measuring method
Measurement pressure range:	Systolic 60 to 290 mmHg 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, 4, 5, 6, 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%
Storage environment:	-20°C to 50°C and 15% to 95% 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 power packs, each 1.2 V and min. 1500mAh (AA, Mignon) 2 x 1.5 V alkaline batteries (AA, Mignon)

Product description









Interfaces:	IR-MED serial or USB (IEM specific) PC combination cable USB or serial Bluetooth
Expected operational life of the device	5 years
Expected operational life of the cuff	6 months

3.7 Symbols






► Note

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

Explanation of the label symbols:

Symbol	Explanation
	Comply with the operating manual!
	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.

Product description

Symbol	Explanation
	The product has a Bluetooth® interface.
	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 IEM for checking!
- 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:

- Isopropanol (70%)
- 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!

Bag: 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 operating manual.

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.

We can offer you to take care of metrological checks and the full service.

This service comprises:

- Metrological checks
- Software updates (if available)
- Functional check: Electronics, pump and pneumatic circuit

Apart from the metrological check, no further maintenance measures for electromagnetic compatibility are necessary.

Power packs:

Power packs are liable to ageing. Power packs 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 power packs supplied by IEM, the capacity and quality of which has been tested. It is important to make sure that the capacity of the power packs is above 1500 mAh.



For further information, please refer to the operating manual for the charger

5 Troubleshooting

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 power packs 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 power packs 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

Error message	Possible cause	Measures
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.
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
	3. Reading not transmitted correctly	3. Start the transmission again.

Error message	Possible cause	Measures
Err 5 bAtt	1. Power pack or battery voltage too low	1. Replace the power packs or batteries
	2. Power packs or batteries defective	2. The power pack or battery voltage is correct but bAtt is shown on the display during cuff inflation. Replace the power packs
	3. Battery contacts are corroded	3. Clean the battery contacts with a cotton cloth and a little alcohol.
Err 6 + 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.

Error message	Possible cause	Measures
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
Err 9 + 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 + 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
<p>The evaluation unit is not reacting to data transfer but co is shown on the display.</p>	<p>1. Data transmission cable has not been inserted properly into the PC.</p>	<p>1. Check whether the 9-pin plug of the data transmission cable is securely located in the device's interface socket.</p>
	<p>2. Also see Err 4</p>	<p>2. Also see Err 4</p>
<p>The Mobil-O-Graph® takes measurements every two minutes.</p>	<p>Log 9 is set in the Mobil-O-Graph®.</p>	<p>Set log 1 or 2 (see chapter 3.4.5 "Specifying the desired measurement log")</p>
<p>The desired log cannot be set with the button combination.</p>	<p>There are still readings from the last patient in the memory</p>	<p>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")</p>
<p>The blood pressure monitor cannot be switched on.</p>	<p>1. The power packs or batteries have been incorrectly inserted</p>	<p>1. Reinsert both power packs or batteries and ensure correct polarity.</p>
	<p>2. The power pack or battery voltage is too low</p>	<p>2. Replace the power packs or batteries</p>
	<p>3. The display is faulty</p>	<p>3. Send the device to your specialist supplier or directly to IEM GmbH for repair.</p>

Error message	Possible cause	Measures
An error occurs during the first measurement.	The cuff size does not fit the arm circumference of the patient.	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
Code 1	Bluetooth interface of the Mobil-O-Graph® did not start up correctly. Possible hardware fault.	Send the device to your specialist supplier or directly to IEM GmbH for checking.
Code 2	The Bluetooth interface of the Mobil-O-Graph® could not be configured correctly. (Communication problem between the Mobil-O-Graph® and Bluetooth module.)	Try it again. If the error persists, send the device to your specialist supplier or directly to IEM GmbH for checking.
Code 3	The status of the Bluetooth interface of the Mobil-O-Graph® could not be determined. (Communication problem between the Mobil-O-Graph® and Bluetooth module.)	Try it again. If the error persists, send the device to your specialist supplier or directly to IEM GmbH for checking.
Code 4	The Bluetooth interface of the Mobil-O-Graph® is not yet connected to the Bluetooth dongle.	Try connecting to the device via Bluetooth® again.

Error indication	Possible cause	Remedy
Code 5	The Bluetooth interface of the Mobil-O-Graph® could not connect to the Bluetooth dongle on the computer.	Try it again. If the error persists, send the device to your specialist supplier or directly to IEM GmbH for checking.
Code 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.
Code 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. If the error persists, please contact your specialist supplier or IEM GmbH.

6 Power packs/batteries

6.1 Operation with power packs

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

Tips:

- Fully charge the power packs before using them for the first time.
- Please note that NiMH power packs only reach their full charge capacity after the 4th charging cycle.
- Recharge power packs again if they have been lying around unused for a long time.
- Do not use power packs that have been stored above 45°C or below 0°C.
- Avoid total discharge in order to protect your power packs.
- If the operating time of the power packs drops significantly, replace all power packs at the same time. Never use old used power packs together with new unused power packs!



Note

Only use the power packs 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 operating manual for 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 power packs (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 power packs (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 power packs can be replaced by the operator.

The normal wear and tear of power packs, 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 operating instructions, 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 power packs, 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 dealer or IEM GmbH directly for repairs and shipping instructions.



ATTENTION

Do not open the casing.

- 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 www.iem.de. 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® NG** and **PWA** 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.
- 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.

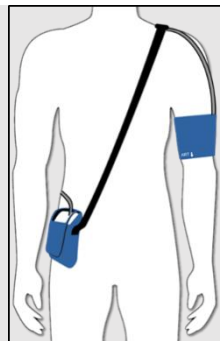


Fig 1: Mobil-O-Graph® with shoulder strap



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.

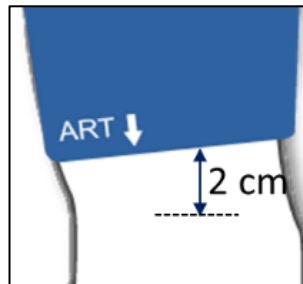
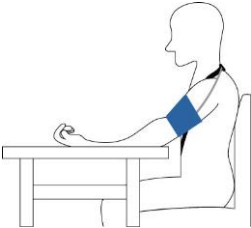
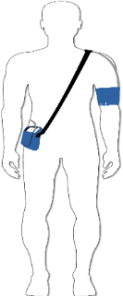



Fig. 2: Positioning of the cuffs

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
		
<ul style="list-style-type: none">▪ Sitting/standing/lying comfortably▪ Not crossing your legs▪ Keeping quiet and not speaking		<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none"> ▪ Switching on and off ▪ Starting and ending measurement (except during the night-time interval) ▪ Removing the interface cable, ending IR communications, establishing and ending Bluetooth communications ▪ Measurement errors
3 tone bursts	<ul style="list-style-type: none"> ▪ System error
Continuous tone bursts	<ul style="list-style-type: none"> ▪ 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 measurement. If the error occurs repeatedly, put the arm cuff on again.
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	If the error persists, 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 neighbouring 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	IEC 60601-1 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	+ - 8 kV contact discharge + - 15 kV air discharge	+ - 8 kV contact discharge + - 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 100 kHz repetition rate	± 1 kV 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

Appendix

Immunity test	IEC 60601-1 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	IEC 60601 test level	Compliance level
Radiated RF disturbance according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m
Conducted disturbances according to IEC 61000-4-6		Not applicable

- ^a The field intensity of stationary transmitters, such as, for example, base stations of mobile telephones and land mobile services, amateur radio stations, AM and FM radio and television transmitters, cannot, theoretically, be accurately predetermined. In order to determine the electromagnetic environment as a result of stationary transmitters, a study of the site's electromagnetic phenomena should be considered. If the measured field strength in the location in which the Mobil-O-Graph® is used exceeds the radio compliance level specified above, the Mobil-O-Graph® should be monitored to verify normal function. If abnormal performance characteristics are observed, additional measures may be necessary, such as, for example, realigning or transposing the Mobil-O-Graph®.
- ^b Within the frequency range of 150 kHz to 80 MHz, field intensity is less than 3 V/m

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 it used only in such an environment.		
Measurement of interference emissions	IEC 60601-1 test level	Compliance level
Radiated RF disturbance according to IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz
	430 - 470 MHz 28 V/m; (FM ± 5 kHz, 1 kHz sine) PM; 18 Hz	430 - 470 MHz 28 V/m; (FM ± 5 kHz, 1 kHz sine) PM; 18 Hz
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	704 - 787 MHz 9 V/m; PM 50%; 217 Hz
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	800 - 960 MHz 28 V/m; PM 50%; 18 Hz
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz