Operating instructions

Ambulatory 24-hour blood pressure monitoring system



for the products:

Mobil-O-Graph® NG Mobil-O-Graph® PWA C€ 0044



Blood pressure monitor Pulse Wave Analysis (PWA)

Analysis unit:
Hypertension Management Software
Client-Server Version 5.1
(HMS CS 5.1)

Dealer:	
EN	_



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1. Introduction

1.1 Foreword

This Mobil-O-Graph® 24-hour Ambulatory Blood Pressure Monitor system (ABPM) provides you with a system using the latest specialist technology, which incorporates all our experience of the past few years with the successful Mobil-O-Graph® ABP monitor. We have also incorporated our customers' wishes into the Mobil-O-Graph®.

The blood pressure monitor, also referred to below as ABP monitor or recorder, can be prepared for a new patient in practice in just a few minutes. This gives you the advantage of using the ABP monitor optimally, and the ability to complete a whole monitoring session each day. The Mobil-O-Graph® will thus quickly be integrated into the daily routine of the practice.

Clinical experience has shown that in addition to the ABPM, analysis of BP self-measurement is also sensible. The client/server data management extension enables a virtual patient clinic to be established.

1.2 Operating Instructions

These operating instructions will show you quickly and simply how to use the ABP monitoring system and its accessories. With a little practice you will see how easy it is to use the ambulatory blood pressure monitor.

For the analysis of the Mobil-O-Graph® the

Hypertension-Management-Software Client-Server

data management is used.

Where reference is made to specific characteristics, only those sections relating to your version are relevant!

Important: The operating instructions describe the ABP monitor and its accessories in the sequence in which you will be setting up the equipment and then using it. After the general description you will find details of installation, setting up, preparation for monitoring, fitting to the patient and evaluation. The individual functions are explained later, at the point at which they are to be used. You will therefore become familiar with use of the blood pressure monitor step by step.

The user should always have the operating instructions at hand.

1.3 Clinical tests

The Mobil-O-Graph® blood pressure monitor fulfils the requirements of the ESH (European Society of Hypertension).

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic or automated Sphygmomanometers.

1.4 CE mark



The Mobil-O-Graph® fulfils the requirements of the Medical Products Directive 93/42/EEC and bears the CE mark.

The Mobil-O-Graph® fulfils the requirements of the R&TTE Directive 1999/5/EU and bears the CE

The declaration of conformity for this product can be downloaded from the I.E.M. website www.iem.de.

This device fulfils the requirements of the standards applicable in accordance with the Directives. In particular, it fulfils the applicable requirements of the following standards:

- 1. EN 1060-1 Noninvasive blood pressure measuring equipment Part 1: General requirements
- 2. EN 1060-3 Noninvasive blood pressure measuring equipment Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

1.5 Scope of delivery

Basic set

- 1. Mobil-O-Graph[®] (NG or PWA)
- 2. S-, M- and L-Cuff
- 3. Mobil-O-Graph® Universal Case
- 4. Recharger including 4 NiMH batteries
- 5. Operating instructions
- 6. Measuring tape
- 7. Event protocol

Analysis unit HMS Client-Server:

- 1. HMS Client-Server on CD
- 2. Bluetooth-Dongle
- alternatively
- 3. IR-MED serial or USB
- alternatively
- 4. PC hybrid cable USB or serial

2. Operating instructions

2.1 Intended use

The appropriate use is 24-hour blood pressure monitoring and pulse wave analysis (PWA). The Mobil-O-Graph® should be used only under medical supervision.

2.2 Incorrect use

Because of the risk of strangulation from the tube and cuff, the ABPM System Mobil-O-Graph® may not be used for patients who are legally incompetent nor for unattended children.

The Mobil-O-Graph® is not designed for the application in neonates and children under the age of 3.

The Mobil-O-Graph® must not be used for blood pressure monitoring during surgeries. It has not been designed for alarm-giving monitoring in intensive care units.

2.3 Indication

The Mobil-O-Graph® ABPM system is intended for clarifying blood pressure and for use as a diagnostic aid. The doctor can, at his or her own discretion, prescribe the use of this medical system for patients if they are suffering from:

- hypertension.
- hypotension,
- borderline hypertrophy,
- ■impaired renal function, or
- require antihypertensive therapy.

2.4 Side effects of 24-hour blood pressure monitoring

24-hour blood pressure monitoring is now a familiar, acceptable and valuable method of measurement, used daily in diagnostic investigation and treatment follow-up.

When considering the use of 24-hour blood pressure monitoring, it is important to check whether the patient is suffering from coagulation disorders or is on anticoagulant treatment. As with occasional blood pressure measurement, petechial bleeding can occur.

In patients on anticoagulant therapy or patients with coagulation disorders, petechial bleeding can occur on the measurement arm in spite of correct cuff fit. The special risk to patients due to anticoagulant treatment or coagulation disorders is present in all cases irrespective of the type of equipment used in measurement.

2.5 Important instructions for the doctor

- A measurement can be stopped at any time by pressing one of the monitor keys. This deflates the
- 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. Attention: The printing ink contains epoxy resin. In hypersensitive patients, the ink can cause allergic reactions in very rare cases.
- Explain to the patient how to place the cuff correctly.
- The equipment must not be used in the vicinity of an MRI scanner!
- The equipment must never be connected to a PC or other unit while still fitted to the patient.
- The use of components not supplied with the equipment can lead to incorrect measurements. Use only accessories offered by IEM.
- The air tube between the Mobil-O-Graph® recorder and the cuff must never be knotted, compressed or stretched.
- Observe the hygiene rules shown in the maintenance schedule.
- Attention: Due to the risk of strangulation with the tube and cuff. the ABPM system must only be applied in children with special care and under the permanent supervision after specific prescription by the doctor.
- Please note that for the application of the pulse wave analysis in children there are currently no clinical studies available against reference methods.
- The pulse wave analysis provides additional indicators for possible risks, but is not admissible or valid as a sufficient indicator for single diseases or therapy recommendations.

■ The shoulder strap or cuff tube can become entangled around the patient's neck and lead to strangulation.

Countermeasures:

The doctor should draw the patient's attention to the fact that the cuff must be worn on the upper arm only and care must always be taken to ensure that neither the shoulder strap nor the air tube can ever become wrapped around the neck. The air tube should therefore always be worn under the outer clothing (even at night).

- If you suspect that water may have entered the unit during cleaning or use of the equipment, the device may no longer be used on the patient. Inform your service engineer without delay or send it for testing.
- The air tube may kink when inflated.
- The doctor should explain to the patient that, particularly when sleeping, the equipment should be positioned in such a way that the tube cannot be compressed. If the patient is not fully competent, the equipment should be worn only under supervision.
- In some patients petechiae, haemorrhages or subcutaneous haematomas may occur. All patients must be told when putting on the cuff that if they experience pain they should switch off the equipment and inform the doctor.
- The doctor must be certain that, according to the health of the patient, the use of the device will not damage blood circulation in the arm.
- The Mobil-O-Graph® is not suitable for use at the same time as high-frequency surgical equipment.
- The Mobil-O-Graph® fulfils the requirements of EMC standards; nevertheless, the Mobil-O-Graph® should not be exposed to strong electromagnetic fields, as outside the limits they may cause malfunction.
- The cuffs and the tube are made of electrically nonconductive material. They thus protect the device from the effects of a defibrillator discharge.
- During a defibrillator discharge the device must not be allowed to touch the patient. The device may be damaged by such a discharge and give inaccurate measurements.
- The device may not meet its performance specifications if stored or used outside the specified temperature and humidity ranges (see section 3.5)
- In the majority of all cases the device is able to function according to specifications in the presence of common arrhythmias such as atrial or ventricular premature beats. In the condition of atrial fibrillation, the device may not be able to function to its specifications.
- Caution: Substitution of a component different from that supplied might result in measurement error.

2.6 Important instructions for the patient

- The beep signals a measurement. Keep still during the measurement, until the process is complete. Let your arm hang loosely or, when sitting, let your lower arm rest on the table or on a support. Avoid moving your hand during the measurement.
- triggers an additional measurement. Press this key only if instructed to do so by your doctor (e.g. after taking medication, if you have chest pains or shortness of breath etc.).
- records the time of an event and triggers a measurement. Press this key only if something important or unusual is happening.
- should be pressed immediately before going to sleep and upon waking. ■ The Day/Night key
- permits the device to be switched on and off if a measurement is not required at the set time. To switch off, press the key for longer than 2 seconds.
- A measurement can be interrupted at any time by pressing any of the keys. This deflates the cuff.

Warnings:

- The cuff may only be worn on the upper arm and in every case you should ensure that neither the shoulder strap nor the air tube can ever become wrapped around your neck. The air tube should therefore always be worn under the outer clothing (even at night).
- Take care to ensure that the tube of the cuff cannot be kinked or compressed, particularly while sleeping.
- If the measurement causes you pain, switch off the device, take off the cuff and inform your doctor.
- The blood pressure monitor must not come into contact with liquids. Do not wear the equipment in
 - If, for example, water has entered the device, it may no longer be used. Switch off the device and take out the batteries.
- Serious malfunctions are indicated by a continuous beep. If a continuous beep sounds, switch off the device, take off the cuff and inform your doctor.
- The cuff connection (air connector) must always engage with an audible click. Otherwise there will be a leaky connection between the Mobil-O-Graph® and the tube that will produce incorrect meas-

You can find a form to copy and give to the patient in the Appendix!

3. Product description

3.1 Introduction

The Mobil-O-Graph® system consists of two principal components:

- the Mobil-O-Graph® NG or Mobil-O-Graph® PWA with different cuffs and further accessories.
- analysis software for the doctor to analyse the measurements.

Measurements from ABP monitor can be interpreted using the analysis unit HMS Client-Server. Using this software, saved measurements can be downloaded to a PC, presented on the screen in various forms, as diagrams, lists and statistics, and printed out.

The Mobil-O-Graph® can then be prepared immediately for the next patient. With a little practice, this procedure can be completed in just a few minutes. This allows the doctor to use the equipment on each working day,

The Mobil-O-Graph® monitoring system is designed to allow recording and display of a blood pressure profile throughout the day and night. Additional parameters are detected, such as nocturnal values and blood pressure variations. This allows the doctor to prescribe the optimum medication for the individual and to monitor the therapeutic outcome.

3.2 Unpacking

All parts supplied are packed carefully for dispatch and checked for completeness and correct function. Should the goods supplied be incomplete or damaged, please notify the supplier without delay.

3.3 The monitor

Components:

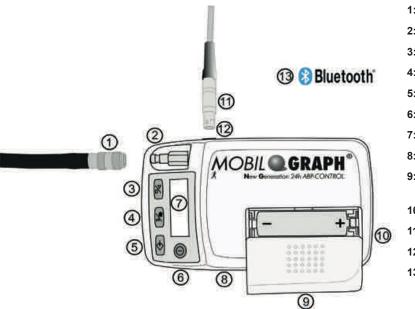


Figure 3.1 Monitor, top view

- 1: Cuff tube/air connector
- 2: Cuff connection
- 3: START key
- 4: DAY/NIGHT key
- 5: EVENT key
- 6: ON/OFF key
- 7: LCD display
- 8: Infrared interface
- 9: Battery compartment cover
- 10: Battery compartment
- 11: PC interface cable
- 12: Data port
- 13: Bluetooth interface (not visible)

3.3.1

All keys are located on the front of the recorder housing (see Figure 3.1 Monitor, top view).

ON/OFF

This key switches the ABP recorder on and off. To prevent switching it on or off by mistake, the key reacts only after 2 seconds.



As with all the other keys, blood pressure measurement can also be interrupted prematurely, causing the pressure in the cuff to be released rapidly (see also the section Warnings).

Caution: Switch the unit on again to continue.

DAY/NIGHT



The DAY/NIGHT key allows waking and sleeping phases to be differentiated when recording, which is important from the point of view of statistical evaluation and graphic presentation. For precise details of the effects on the printout, please see the relevant sections on analysis.

Briefly: the patient is instructed to operate the "DAY/NIGHT" key on going to bed and again when getting up in the morning. This adjusts the monitoring interval to suit the individual patient and helps you in assessing the BP profile. As well as adjusting the interval, the appropriate notes are shown on the printout. If this key is not operated, the change in interval will take place according to the protocol selected.

FVFNT



This key allows the patient to record the time at which medication is taken or any events happen that may cause blood pressure to rise or fall.

Pressing this key directly triggers a measurement. The patient should note the reason for pressing the Event key in the events diary.

START



This key starts the 24-hour measurement period and also allows a measurement outside the pre-set measurement cycle.

Caution: The result of the first measurement should be checked by the doctor for plausibility, to ensure that the subsequent automatic measurements are correct, and that the cuff fits properly. If the measurement is incorrect, the instructions in the sections Preparing for monitoring and Troubleshooting should be followed.

> When the Start key is pressed, the number of measurements recorded so far is displayed and manual measurement begins. This differs from automatic measurement according to the monitoring protocol, in that the cuff is inflated in stages. This determines the cuff pressure required to allow the systolic blood pressure to be measured. This maximum inflation pressure is stored and is then approached immediately by direct inflation for the subsequent automatic measurements.

> The patient can use the Start key to take manual measurements in addition to the pre-set measurement cycle.

3.3.2 Display

The LCD display is located on the front of the recorder housing (see Figure 3.1 Monitor, top view). It displays useful information for the doctor and patient on measurement data, monitor settings and measurement errors.

3.3.3 Acoustic signals

The acoustic signals used consist of single or multiple beeps.

The following signals are emitted:

1 beep	Switching on or off, start and completion of a measurement (except for night intervals), removal of interface cable, end of IR communication, set-up and end of Bluetooth communication, and measuring error
3 beeps	System error
Continuous beep	Serious system error (e.g. cuff pressure is greater than 15 mmHg for more than 10 seconds outside of a measurement)
Combined beeps	When deleting measurements manually, first one beep is emitted and 2 seconds later 5 beeps.

3.3.4 **Cuff connection**

The cuff connection is fitted on the front of the recorder housing (see Figure 3.1 Monitor, top view). This metal plug is used to connect the recorder with the cuff via the cuff tube and the metal cuff socket.

Important: Both the doctor and the patient should be aware that the metal plug (air connector) must always engage with an audible click. Otherwise there will be a leaky connection between the Mobil-O-Graph $^{\! \otimes \! }$ and the tube that will produce incorrect measurements.

3.3.5 Data port

The data port is located on the left-hand side of the housing (see Figure 3.1 Monitor, top view). The connector cable supplied goes into this socket. This is a plug-in connection, i.e. the red dot on the plug must be aligned with the red dot on the socket. To disconnect, pull on the outer metal ring of the plug (see section: The analysis unit)

3.3.6 Infrared interface

The infrared interface provides an equal, wireless alternative to the data port. To use this interface you will need the PC infrared interface IR-Med. The infrared interface can be obtained from your specialist dealer (see section: The analysis unit).

3.4 Preparing for monitoring

- Connect the cuff tube with one of the cuffs supplied, by pushing it onto the plastic connector.
- Connect the cuff tube with the socket on the front of the recorder housing
- First check that the batteries have been inserted correctly. You should always use fully charged batteries for a new monitoring session. Alternatively, you can use alkaline batteries. Take care to insert the batteries the right way round.

Important: Use only the I.E.M. NiMH rechargeable batteries supplied or alkaline batteries. Although zinc-carbon batteries and NiCd rechargeables show adequate voltage in the battery test, the output is often insufficient to carry out monitoring over a 24-hour period.

> The rechargeable batteries should be discharged and recharged several times before they are first used. Please follow the instructions for use enclosed with the charging unit.

> To perform monitoring over a 48-hour period, you need 2 additional batteries to exchange after 24 hours

3.4.1 Switching on

Always check the condition of your recorder first, before you give it to a patient. You can do this by observing the initial displays shown on the recorder shortly after switching it on.

The following sequence of displays should appear:

Test	Display	Commentary
Battery status (Volts)	2.85	(for NiMH rechargeable batteries min. 2.75; for alkaline batteries min. 3.10)
Display Segment Test	999:999 to 000:000	Along with the numbers, all the other LCD symbols are shown. Check whether all segments are being shown correctly and completely (the complete code is constantly being checked for correctness in the background)
Current 24-hour time	21:45	(Example)

If a fault occurs during the internal test, the recorder shows E004 on the display and emits an acoustic signal. For safety reasons, use of the recorder is blocked. Return the recorder to your specialist dealer or directly to I.E.M. GmbH for repair without delay.

3.4.2 Clearing the memory

The memory must be cleared before each monitoring session, i.e. no blood pressure data from the previous patient must be left in the memory. However, should values still be present, you can delete them with the delete function of the analysis software.

You can delete the memory manually by pressing and holding down the start button for at least 5 seconds. While holding down, all segments of the LCD are highlighted followed by a single beep. Subsequently the number of the recordings is shown, followed by "clr". If the event button is pressed within 5 seconds and held down for at least 2 seconds, all recordings will be deleted.

3.4.3 Setting the time/date

The Mobil-O-Graph® has an internal buffer battery that allows the clock to continue running even after the batteries have been removed. You should nevertheless check the time and date before each measurement series.

The time and date can be set with the analysis software. You can also set the time and date manually by holding the Start key and then pressing the Event key. Now you are in the "Set time" mode. Use the Start key to change the number in question, and use the Event key to jump to the next.

3.4.4 Transmitting patient data (ID)

The Monitor must be prepared by transmitting the patient data (ID), so that measurements are allocated correctly when reading out (see 4.8.3, Importing a patient ID).

3.4.5 Specifying the measurement protocol required

You have the option to select from eleven (1-11) protocols.

Once you have completed one measurement, the protocol cannot be changed until deletion of all data has been completed.

The protocols can be set using the analysis software.

You can set the protocols manually by holding down the Day/Night and then pressing the Event key. Use the Start/Stop key to change the protocol, and confirm with the Event key.

Protocol	Day time	Night time	Measurements per hour	Acoustic signal	Measurements shown on display
1	08:00	23:59	4	YES	YES
	00:00	07:59	2	NO	
2	08:00	22:59	4	YES	YES
	23:00	07:59	1	NO	
3	07:00	21:59	4	YES	NO
	22:00	06:59	2	NO	
4	08:00	23:59	4	YES	NO
	00:00	07:59	2	NO	
5	18:00	09:59	4	YES	YES
	10:00	17:59	2	NO	
6	07:00	23:59	4	YES	YES
	00:00	06:59	2	NO	
7	06:00	22:59	4	YES	NO
	23:00	05:59	2	NO	
8	07:00	08:59	6	YES	YES
	09:00	23:59	4	YES	
	00:00	06:59	2	NO	
9	09:00	08:59	30	NO	YES
10	08:00	07:59	30	YES	NO
11	08:00	23:59	4	YES	YES
	00:00	07:59	2	NO	

Table 3.0 Protocol list

Note:

Protocols 1, 2 and 10 are provided as defaults, but they can be modified using the analysis software (see 4.8, prepare measurement device). Protocol 5 is suitable for nighttime activity (night shift). Protocol 9 is the Schellong-test.

Protocol 10 transmits the values automatically after each measurement to your doctor's PC via Bluetooth, or to a database via mobile communications such as a mobile phone or modem (preconfigured by I.E.M.; see 4.8.1, Setting the measurement protocol). Only preconfigured mobile phones or modems can send the data via GPRS as a block of data.

Protocol 11 is only available for the Mobil-O-Graph® with integrated 24-h-PWA and the HMS CS as of version 4.0. Here, the intervals for blood pressure monitoring and 24-h-PWA can be configured independently

3.4.6 Putting on the monitor and starting measurement

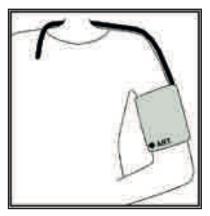


Figure 3.2 Putting on the cuff

Put the equipment pouch on the patient. By varying the length of the strap you can use it either as a hip belt or a shoulder strap. Alternatively, use a normal belt that matches the patient's clothing. Now fit the cuff on the patient; correct cuff fit is extremely important for accurate measurement (see *Figure 3.2*).

The cuff can also be worn over the shirt or blouse. We recommend that the cuff be fitted on the bare upper arm. In this case, bring the tube out between the buttons of the shirt or blouse, around the back of the neck to the ABP monitor on the right-hand side.

Please note the following points:

IMPORTANT:

- 1. When putting the recorder on the patient, the recorder must not be connected to other external equip-
- The cuff must fit so that the air tube cannot be kinked or compressed at any point. The tube connection on the cuff should therefore be directed upwards. The air tube should allow free movement of the upper arm and should run over the back of the neck to the other side of the body.
- 3. It is essential to ensure that the artery symbol lies over the brachial artery. When the cuff fits correctly, the metal strip is on the outer side of the upper arm (elbow side).
- 4. The material loop must cover the skin under the metal strip.
- 5. The lower edge of the cuff should be about 2 cm above the bend of the patient's elbow.
- 6. The cuff should fit relatively snugly on the upper arm. Correct fit can be checked by a simple test: there should be room to slip one finger under the cuff.
- 7. The correct cuff size is also important if blood pressure is to be measured correctly. To obtain reproducible results, standardised monitoring conditions are required, i.e. the cuff must be the correct size for the patient. Using the tape measure supplied, measure the circumference at the middle of the upper arm and select the appropriate cuff:

Upper arm circumference	Cuff
14 - 20 cm	XS
20 - 24 cm	S
24 - 32 cm	М
32 - 38 cm	L
38 - 55 cm	XL

- 8. Connect the air tube from the cuff to the ABP recorder. Push the tube firmly over the connection until a click is heard as it engages; to disconnect, simply pull back the outer metal ring on the plug.
- 9. The recorder is now correctly fitted and ready for use.

Once all these steps have been completed, the monitor can be started. First, a manual measurement must be carried out by pressing the "START" key. This measurement is used to determine whether the recorder is work-

If errors occur, check once more that the procedure followed in setting up and fitting the equipment was correct. Should this not solve the problem, repeat the setting-up procedure.

Only after a successful manual measurement can the patient be allowed to leave with the equipment.

Interrupting measurements

During a measurement. ANY key can be used to interrupt the measurement. The display then shows "-StoP-" and beeps 5 times. The process is also saved in the table of measurements under "Interruption".

Important: Before beginning a 24-hour monitoring session, take the patient through Chapter 2: Operating instructions.

3.5 Technical data

Pressure measurement range:	Systolic 60 to 290 mmHg Diastolic 30 to195 mmHg
Accuracy:	+/- 3 mmHg in the range indicated
Static pressure range:	0 to 300 mmHg
Pulse range:	30 to 240 beats per minute
Method:	oscillometric
Measurement intervals:	0, 1, 2, 4, 5, 6, 12 or 30 measurements per hour
Monitoring protocols:	2 modifiable interval groups
Storage capacity:	300 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
Dimensions:	128 x 75 x 30 mm
Weight:	approx. 240 g including batteries
Power supply:	2 NiMH batteries, each 1.2 V and at least 1500 mAh (AA, Mignon) 2 alkaline 1.5 V batteries (AA, Mignon)
Interfaces:	Serial (cable) Infrared IEM-specific Bluetooth (Class 1/100 m)

3.6 Symbols

Battery symbol

2 x 1.5 V Mignon AA 2 x 1.2 V NiMH ACCU Meaning: The symbol shows the type of voltage.

Disposal of used electrical and electronic appliances



Meaning: This symbol on a product or its packaging indicates that the product should not be treated as normal household waste, but must be returned to a recycling point for electrical and electronic appliances. You can obtain further information from your local authority, local waste disposal plants or specialist dealers.

Defibrillator rating



Meaning: BF applied part, defibrillator protected

Caution, consult accompanying documents



Meaning: caution, consult accompanying documents

Manufacturing date



Meaning: Date of manufacture

CE mark



Meaning: The device fulfils the basic requirements of the European Directives on medical devices.

4. Hypertension Management Software Client-Server

The monitor measures blood pressure and stores the measurement. On completion of measurements, the stored measurements are transferred to your computer. You can then analyse the measurements according to your requirements.

The patient file contains important data such as:

- Personal patient ID number (mandatory entry)
- Name (mandatory entry)
- Address, telephone number
- Personal data (age, sex etc.)
- Medication, medical history, emergency contacts

The HMS CS program offers you various options for analysis. You can choose to display the results on your screen or print them out directly as:

- ■4.11.1, Table of measurements
- Statistical analysis with mean blood pressure values for the whole day, and for the daytime and nighttime periods and the first hour after waking, plus hourly mean values, see 4.11.7, Report
- Extreme values (maximum and minimum values), see 4.11.7, Report
- Percentage incidence of values above a predetermined limit, see 4.11.7, Report
- Standard deviation (variability), see 4.11.8, Hourly mean values
- Calculation of day/night reduction, see 4.11.7, Report
- Graphs such as:
 - □ Envelope curve of hourly mean values, see 4.11.2, BP profile
 - □ Correlation, see 4.11.4, Correlation
 - □ Pie chart of percentage of values above limit, see 4.11.5, Values above limit
 - □ Bar chart of measurements, see 4.11.6 Frequency distributions
- □ Curve of changes in blood pressure, see 4.11.9, Changes in blood pressure
- □ Curve of measurements, see 4.11.9, Changes in blood pressure
- ☐ Histogram of blood pressure distribution, see 4.11.9, Changes in blood pressure
- □ Curve comparison for optimising treatment, see 4.11.9, Changes in blood pressure

In this way you can rapidly and simply visualise the course of and fluctuations in blood pressure over the day and night. You can adjust medication to take the best possible account of these changes.

You can also enter measurements from the "Klock®" - the wrist blood pressure monitor - and the Stabil-O-Graph - the upper arm blood pressure monitor - and manage the data using the HMS CS program (see 4.11.3, Selfmeasurements). An infrared eye is required for data transfer.

The HMS CS also provides the opportunity to establish an E-Health Service (telemedicine), with a significantly higher security for the patient, while saving work for the doctor.

You can set limits, or define alarms that will only inform you if the limits you have set are exceeded (e.g. by

The offers include blood pressure monitoring by the Stabil-O-graph mobil and weight monitoring with the scale

In addition to an online database, you can use these devices to synchronise and manage data online with the HMS CS online.

For further information, please contact your specialist dealer or I.E.M. GmbH directly.

4.1 Using HMS CS

Basic knowledge and experience of the operating systems Windows®, Macintosh® or Linux® are required for using HMS CS.

Use the HMS CS program to manage blood pressure monitoring data and evaluate them. You classify these measurements by patient. You can store as many measurement series as you like for each patient. Each measurement series consists of many single measurements.

HMS CS will run through the following steps:

- Before 24-hour monitoring: prepare measurement
- 1) Start HMS CS
- 2) Select patient or enter new patient
- 3) Connect monitor to HMS CS

- 4) Prepare monitor
- 5) Quit HMS CS.
- After 24-hour monitoring: Process data
 - 1) Start HMS CS
 - 2) Connect HMS CS to monitor
 - 3) Read out measurements from the recorder
 - 4) Analyse data
 - 5) Quit HMS CS.

4.2 Installing the software

The software is able to communicate with the monitor via different interfaces. The following connections are possible:

- Cable with serial interface (e.g. COM1,2...),
- Combi cable with USB interface,
- Infrared (IR) with serial interface,
- Infrared (IR) with USB interface,
- Bluetooth.

Important: If you are using the USB interface and/or Bluetooth, you must **first** install the corresponding driver. You can find the details below.

Note: Please insert the USB adaptor (USB stick or cable with USB interface) only **after** installing the software onto your computer, or when prompted to do so.

4.2.1 System requirements

- 1) Computer
 - ■1 GHz
 - ■1 GB RAM
 - 200 MB hard disk storage
 - 1024x768 pixels
 - Two spare USB ports

2) Operating system

- a) Windows® 7, Windows® 8, Windows® 8.1, Windows® 10, Windows Vista® (32-bit & 64-bit)
- b) Macintosh® OS X 10.7.5 (64-bit)
- c) Linux Ubuntu 14.04 (64-bit)

3) Software

Java Runtime Environment (JRE is supplied with the installation CD)

4) Bluetooth

- ■Bluetooth USB adapter
- Bluetooth 2.0 or higher
- USB Version 2.0 or higher
- BlueSoleil driver or software must not be installed!
- Tested USB adapters:
 - DIGITUS USB-Adapter BT 4.0
 - HAMA Nano v2.1

4.2.2 Installation for Windows®

Note: Please insert the USB adaptor (USB stick or cable with USB interface) only after installing the software onto your computer, or when prompted to do so.

Important: If you are using the USB interface and/or Bluetooth, you must first install the corresponding driver.

Procedure:

- 1) Install application from CD-ROM
- 2) If necessary, install drivers from CD-ROM in the following order:
 - first Bluetooth driver.
 - then USB driver.
- 3) Insert USB adaptor and/or Bluetooth adaptor into the computer.

Installing the application from CD-ROM

▶ Insert the CD into the CD-ROM drive.

The installation program will normally start automatically. If it does not (autorun function has been switched off),

- □ open the CD-ROM drive in Windows Explorer and
- □ click the file CD_Start.exe, to start installation.
- Select your language.
- In the installation menu, click HMS-CS Setup.

The installation wizard will appear.



Follow the instructions on the screen.

Installing the Bluetooth driver

Note: Please insert the Bluetooth adaptor only after installing the software onto your computer, or when prompted to do so.

For the Bluetooth-Adapter DIGITUS no driver software is needed.

- In the installation menu, click Bluetooth driver
- Follow the instructions on the screen.

Installing USB driver

Note: Please insert the USB adaptor (USB stick or cable with USB interface) only after installing the software onto your computer.

- ▶ In the installation menu, click USB cable driver
- ► Follow the instructions on the screen.

Installation of the software is now complete.

4.2.3 Installation for Macintosh® OS X 10.7.5 and later

Procedure:

- 1) Install application from CD-ROM
- 2) Insert USB adaptor and/or Bluetooth adaptor into the computer.

Installing application from CD-ROM

▶ Insert the supplied CD into your CD-ROM drive.

The CD symbol HMS CS appears on the desktop.

▶ Double-click this CD symbol for HMS CS.

The CD-ROM opens.

- Open the directory Mac_10-7-5.
- ▶ Drag the file *HMS.app* into your Applications folder.

Installation of the software is now complete.

4.2.4 Installation for Linux

Procedure:

- 1) Install the application from the CD-ROM
- 2) Plug Bluetooth adapter and/or USB adapter into your computer.

Install the application from the CD-ROM

- ► Log in as System Administrator (root).
- ▶ Place the CD supplied into your CD-ROM drive.
- ▶ On the CD, open the Linux directory.
- ► Copy the HMS CS folder into your Home directory.
- Set the HMS CS file in the Home directory to executable.
- Set up a link to the HMS file on your desktop.

Software installation is now complete.

On the installation CD, the "Docs" directory contains various documents (first steps, brief instructions, user manual). "index.htm" shows the available documents.

4.2.5 Hypertension Management Software update

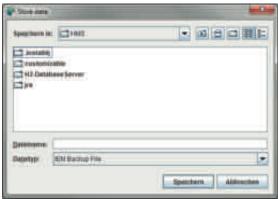
Updating an already installed version of the Hypertension Management Software to the latest version is no different from installing the software from scratch. Settings which have already been selected are not changed during an update. With regard GDT (German communication standard), HL7 and network settings, the user does not need to do anything when carrying out an update. Before updating the Hypertension Management Software, however, it is recommended that you back up the data, but this is not mandatory.

4.2.6 Data back-up

Back up data

To back up your data, proceed as follows:

- 1) Launch your Hypertension Management Software.
- 2) In the menu bar, click on Data -> Data back-up and Back up data.
- 3) The Back up data window appears.

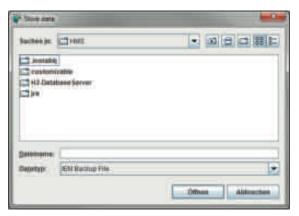


- 4) Enter a filename and location to save the data you are backing up.
- 5) Click Save.
- 6) Your data is backed-up.

Restore data

To restore your data, proceed as follows:

- 1) Launch your Hypertension Management Software.
- 2) In the menu bar, click on Data -> Data back-up and Restore data.
- 3) The Back up data window appears.



- 4) Select the appropriate file containing your backed-up data.
- 5) Click Open.
- 6) Confirm that you wish to restore your data.
- 7) Your data is restored.

4.3 Starting and quitting HMS CS

Basic knowledge and experience of the operating systems Windows $^{\otimes}$, Macintosh $^{\otimes}$ or Linux $^{\otimes}$ are required for using HMS CS..

Starting the program

► On the desktop, double-click
HMS CS starts up. Information about the progress of loading the program appears (e.g. program version, progress bar).

Quitting the program

► In the work window, in the toolbar at the top, click

If you have previously modified data, you will be asked if you want to save the data.

Information about the progress of quitting appears.

4.4 Structure of HMS CS user interface

You can access all functions from the control window. More windows may appear depending on the function.

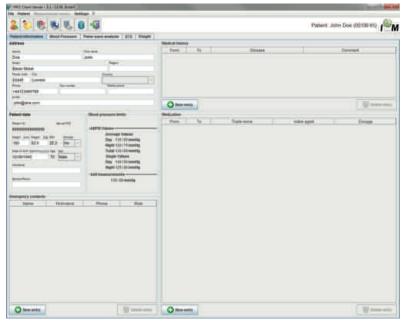


Figure: control window with Patient information tab.

You can call up functions in the Menu bar at the top of the window. The Toolbar directly under the Menu bar contains buttons (symbols) for individual process steps. The task panel contains the two tabs Patient information and Measurements.

4.4.1 Menu bar

At the top of the control window is the Menu bar.

File Patient Measurement series Settings ?

Each menu item combines functions.

■ Menu File

Menu item	Function	
Patient list	Display list with existing patients	
New Patient	Setup new patient	
Import	Import of patient data (Abdm.mdb, GDT and patient)	
Data back-up	Storing and restoring of database	
	(Warning: By restoring the database the existing data will be replaced with the – saved database – danger of data loss.)	
Audit trail	Record of all changes made in patient data	
Quit program	Quit HMS CS	

■ Menu Patient

Menu item	Function	
Delete	Delete current patient, including all measurements, see 4.6.5, <i>Deleting a patient</i>	
Export	Manual export of patient to the e-health database	
Change ID	Change personal patient number of the currently modified patient, see 4.6.4, Change Personal Patient Number (Patient-ID)	
Export Patient	Manual export of a patient to the e-health database	
Delete modification	Reverse modifications on a currently opened patient data base	

■ Menu Measurement series

Menu item	Function
Export (Excel)	save the currently selected test series in an Excel file, see 4.9.5, export test results
Export (XML)	save the currently selected test series in an XML file, see 4.9.5, export test results
Export (GDT)	save the currently selected test series in a GDT file, see 4.9.5, export test results
Delete	Delete selected measurement series

■ Menu Settings

Note: for detailed information see 4.12, Setting standard values for HMS CS

Menu item	Function
Database	Configuring database, only for experienced users!
Language	Setting the language of the program
e-Health service	Establishing connection to e-Health service
Interfaces	Setting interface for recorder
BP limits	Setting limits for analyses
Analysis	Specify settings for analysis
Colours	Setting colours for curves and background in graphs
Extras	Procedure for calculations, display and Bluetooth
GDT Settings	Specify file and folder settings for the GDT import/export

■ Menu ?

İ	Menu item	Function
	About	Display information about HMS CS version

4.4.2 Toolbar

At the top of the control window, below the Menu bar is the Toolbar. It contains buttons (symbols) for calling up important functions quickly. On the far right you will see the current patient's name and date of birth.



Tip: If your mouse pointer hovers over a symbol, a brief explanatory text will appear (Tooltip).

Symbol	Meaning	Function
2	New patient	Enter a new patient, see 4.6.1, Entering new patient
	Patient list	Display list of existing patients, see 4.6.2, Selecting existing patient
8	Prepare device	Program recorder for the next 24-hour monitoring period
	Read out device	Read out measurements from the recorder
3	Start PWA	A pulse wave analysis will be started in the Mobil-O-Graph [®] .
	Bluetooth	red: Bluetooth not active green: Bluetooth active
3 9	e-health symbols	Export current patients to the e-health data base. Synchronize current patients with the e-health data base.
*	Quit program	Quit HMS CS
4	Practice Monitoring	Receive test series via the Practice Monitoring

Note: You can call up some of these functions via menu items in the Menu bar.

4.4.3 Using the mouse

Click means: click the left mouse button once.

Double-click: click the left mouse button briefly twice.

4.5 First steps with a sample patient

Once you have successfully installed HMS CS, you can try out important functions using the sample patient John Doe.

Basic knowledge and experience of the operating systems Windows®, Macintosh® or Linux® are required for using HMS CS.

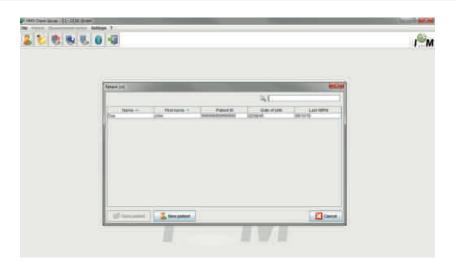
On the desktop, double-click



HMS CS starts up. Information about the progress of loading the program appears (e.g. program version, progress bar).



The control window and the window Patient list appear.

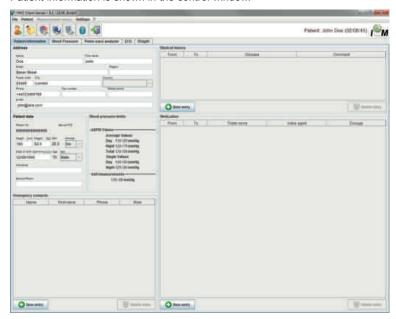


4.5.1 Displaying sample patient

Click the line containing Doe, John and then

Tip: It is even quicker to double-click the line.

Patient information is shown in the control window.



Top right in the window you will see the patient's name and date of birth.

The **Patient information tab** contains several fields: address, patient data, emergency contacts, medical history and medication.

4.5.2 Displaying sample patient's data

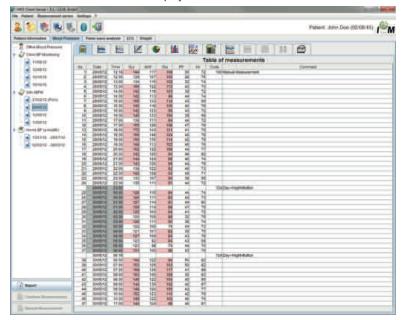
► Click on the *Measurements* tab header.

The Measurements tab contains, on the left, a list of the monitoring sessions already performed.



► Click a monitoring session

Its Table of measurements is displayed.



The highlighted values are measurements that lie outside the defined limits (see 4.12, Setting standard values for HMS CS).

▶ To display further analyses, click the header of the analysis you wish to see.

Tip: If your mouse pointer hovers over a tab header, a brief explanatory text will appear (Tooltip).



You can find further information about analyses under 4.11, Analysing measurements.

4.5.3 Quitting HMS CS

► In the toolbar at the top, click

If you have previously modified data, you will be asked if you want to save the data. Information about the progress of quitting appears.



The HMS CS control window disappears.

4.6 Editing patient data

Patient information is stored in a database. You can

- Enter new patients, see 4.6.1, Entering new patient
- Editing data from stored patients, see 4.6.2, Selecting existing patient
- Import patient information for existing patient from another source.

You can edit all patient information after recording it at any time.

4.6.1 Entering new patient

► In the toolbar, click

The window New patient appears.

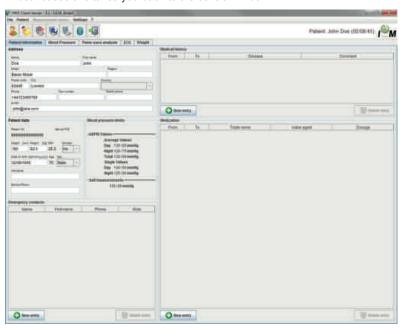


Patient ID and Surname are mandatory fields (both details are criteria for searching and sorting), all the other details are optional.

Tip: Use the tab key to jump from one field to the next.

- To save the new patient, click <u>Y</u>es Confirm with
- Cancel To discard the new patient, click

In both cases this takes you back to the control window.



The Patient information tab contains several fields: address, patient data, emergency contacts, medical history and medication.

4.6.2 Selecting existing patient

Select a patient from all the patients entered in HMS CS, in order to

- view his/her previous measurements,
- prepare the monitor for this patient,
- or to import the values from a 24-hour monitoring session that has just ended from the recorder into HMS CS.
- ► In the toolbar, click

The window Patient list with all the patients entered in HMS CS appears.



If you see the required patient in the window,

► click the list entry and then

Tip: It is even quicker to double-click the list entry.

This takes you back to the control window (for how to proceed further see 4.6.3, Supplementing or modifying patient data).

To find one patient among many,

- ▶ In the top right search field, enter surname, forename or Patient ID.
 During your entry, HMS CS will search the database and display the patients found.
- ► click the list entry and then

Tip: It is even quicker to double-click the list entry.

This takes you back to the control window (for how to proceed further see 4.6.3, Supplementing or modifying patient data).

If you do not find the required patient,

Click New patient

The window New patient appears (for how to proceed further see 4.6.1, Entering new patient).

4.6.3 Supplementing or modifying patient data

- ▶ To modify an address or patient data, type the new details in the respective fields.
- ► To add emergency contacts, medical history and medication, click

 Another window appears.
- ► Type the new details into the respective fields.
- ► To import the new data, click

 The window disappears.

4.6.4 Changing patient ID number

▶ In the menu bar, click **Patient** and then **change ID**.

The window Change patient ID appears with the current patient's number.



- ► Change the Patient ID.
- Click Save

4.6.5 Blood Pressure Limits

- ► Click on the Patient Information tab on
- ► Specify the blood pressure values for the current patient in the opened editing window. Upon exceeding the limits the test results will be marked respectively in the analysis.

4.6.6 Deleting a patient

- ▶ In the menu bar, click Patient and then delete.
- Confirm with

The current patient is deleted, including all measurements.

4.6.7 Enter office measurements BP

The special measurement series **office measurements BP** is designed for recording BP measurements that you as a doctor or patient have made using your own device.

- To save these measurements in HMS CS, you can type in values the patient has provided,
- Values recorded by the Stabil-O-Graph[®] monitor can be directly imported by infrared data transmission (see 4.10, Using the Stabil-O-Graph[®] (optional)),
- Values recorded by the Stabil-O-Graph[®] mobil monitor and transmitted to the IEM server can be called up via synchronization with the IEM server (for further information, please contact your specialist dealer or I.E.M. GmbH directly).

To enter measurements yourself,

- ▶ In the control window click the *Blood Pressure* tab.
- ▶ Click on Practice Measurement on the left of the list and then on Manual Measurement.



- ► Type the measurements, date and time in the window Manual BP measurement.
- Click Save

4.6.8 Enter office measurements weight

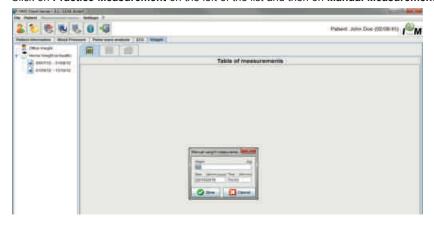
The special measurement series office measurements is designed for recording weight.

To save measurements in HMS CS, you can type in self-measured values,

- you can type in self-measured values,
- Values that the patient's scales have recorded and transmitted to the IEM server can be called up via synchronization with the IEM server (for further information, please contact your specialist dealer or I.E.M. GmbH directly).

To enter measurements yourself,

- ▶ in the control window click the *Weight* tab.
- ► Click on Practice Measurement on the left of the list and then on Manual Measurement.

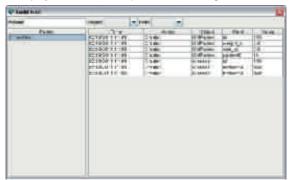


▶ In the window Manual weight measurement type in weight, date and time.



4.6.9 Audit trail

To display the record of all patient data changes, click Audit trail in the File bar.



4.7 Using the Mobil-O-Graph[®] blood pressure monitor

4.7.1 Connection via cable

When using the Mobil-O-Graph® monitor with cable connection, follow these steps:

- Connect the monitor to the PC,
- Configure the monitor in HMS CS
- Set the monitor for the patient using HMS CS,
- Test the monitor and put it on the patient.

After 24-hour monitoring session

- Take the monitor off the patient and connect it by cable to the PC,
- Read out measurements from monitor and save them in HMS CS under patient information.

Connecting the PC with the Mobil-O-Graph® by cable

Step	Mobil-O-Graph [®]	PC	
1)	► Switch off the Mobil-O-Graph®		
2)	Establishing a connection between Mobil-O-Graph® and PC		
	a) via serial interface (COM1,2) with cable or co	mbi cable	
		► Switch off the PC	
		Connect the cable to the serial interface (COM1,2)	
		► Switch on the PC.	
	b) via USB interface	B interface	
		► Connect the cable to a USB port.	
3)	Insert the plug into the data port on the left- hand side of the housing until it engages.		
	Note: The red dot on the plug must be aligned with the red dot on the data port.		
	Caution: Do not force it!		
4)	► Switch on the Mobil-O-GraphNG®		
	co appears on the display		

Configuring interface between Mobil-O-Graph® and HMS CS

Starting situation:

- Monitor is connected to the PC,
- Mobil-O-Graph[®] is switched on,
- ■PC is switched on.

Step	Mobil-O-Graph [®]	PC
1)		► Start HMS CS.
		If the program is set up for this, the window Patient list will appear (see 4.12.7, Extras). In this case, select a patient (see 4.6.2, Selecting existing patient)
		In the Menu bar click Settings and then Interfaces.
		► In the window Interfaces click the Serial/IR/ USB tab.
		➤ Set COM1,2 as the interface (see 4.12.4, <i>Interfaces</i>)

Preparing the Mobil-O-Graph® for 24-hour monitoring

Starting situation:

- Monitor is connected to the PC,
- Mobil-O-Graph® is switched on,
- ■PC is switched on,
- Mobil-O-Graph® interface recognises HMS CS.

Step	Mobil-O-Graph®	PC
1)		► Start HMS CS.
		▶ Display the patient (see 4.6.1, Entering new patient and 4.6.2, Selecting existing patient)
		► In the toolbar, click
		Caution: If battery voltage is insufficient for 24-hour monitoring, a message will appear. Please note this information!
		The window Prepare monitor appears.
		Set the protocol for 24-hour monitoring (see 4.8.1, Setting the measurement protocol).
		► Click Set clock of device
		► Click Send Patient ID
		► Click Send and activate.
		► Click Close
		► In the toolbar, click
		► The program quits
2)	► Switch off the Mobil-O-GraphNG [®]	
	Disconnect cable (pull the plug from the data port).	

Begin 24-hour monitoring

Starting situation:

■The monitor should be disconnected from the PC.

Step	Mobil-O-Graph [®]	PC
1)	Put the monitor on the patient (put on the cuff and connect it to the recorder).	
	► Switch on the Mobil-O-Graph [®] .	
	On the display appears the time set.	
	Press for a manual measurement, to ensure that the monitor works as it should.	
	► Wait for the first, manual measurement.	
	If everything is in order, the patient can leave.	
	A successful measurement is necessary to activate the protocol!!	

After 24-hour monitoring, connect PC with Mobil-O-Graph $^{\! 8}$ via cable

After 24-hour monitoring, send the data from the recorder to HMS CS.

Starting situation:

■ Mobil-O-Graph[®] is on the patient's arm and is switched on.

Step	Mobil-O-Graph [®]	PC
1)	► Switch off the Mobil-O-Graph®	
	► Take the monitor off the patient (take off the cuff and disconnect the recorder).	
2)	Establish a connection between Mobil-O-Graph® an	d PC
	a) via serial interface (COM1,2) with cable or co	mbi cable
	If the cable is no longer connected to the PC:	
		► Switch off the PC
		Connect the cable to the serial interface (COM1,2)
		► Switch on the PC.
	b) via USB interface	
		► Connect the cable to a USB port.
3)	Insert the plug into the data port on the left- hand side of the housing until it engages.	
	Note: The red dot on the plug must be aligned with the red dot on the data port.	
	► Switch on the Mobil-O-Graph [®]	
	co appears on the display	

Read out measurements from 24-hour monitoring from Mobil-O-Graph®

Starting situation:

- Monitor is connected to the PC,
- Mobil-O-Graph® is switched on,
- ■PC is switched on,
- Mobil-O-Graph[®] interface recognises HMS CS.

Step	Mobil-O-Graph [®]	PC
1)		► Start HMS CS.
		If the program is set up for this, the window Patient list will appear (see 4.12.7, Extras). In this case, select a patient (see 4.6.2, Selecting existing patient)
		► In the toolbar, click
		The question appears: Assign measurements to patient with ID number xxx?
		► Click <u>Yes</u>
		The question appears: Delete patient ID and measurements from the recorder?
		► Click <u>Yes</u> .
		After data transmission the window Measurement series appears.
		If necessary, change the times for the daytime and night intervals.
		► Click Save
		The transmitted measurements are displayed as a Table of measurements.
2)	► Switch off the Mobil-O-Graph [®]	
	Disconnect cable (pull the plug from the data port).	

For further analysis of the measurement series see 4.11, Analysing measurements.

4.7.2 Connection via Bluetooth®

When using the Mobil-O-Graph® with a Bluetooth connection, follow these steps:

- Configure monitor in HMS CS,
- Set the monitor for the patient using HMS CS,
- Test the monitor and put it on the patient.

After 24-hour monitoring

- Take the monitor off the patient,
- Read out measurements from the recorder and save them under patient information.

Configuring interface between Mobil-O-Graph® and HMS CS

Starting situation:

- important: Bluetooth driver is installed!
- PC is switched on.

Step	Mobil-O-Graph [®]	PC
1)		► Start HMS CS.
		If the program is set up for this, the window Patient list will appear (see 4.12.7, <i>Extras</i>). In this case, select a patient (see 4.6.2, <i>Selecting existing patient</i>)
		In the menu bar, click settings and then Interfaces.
		► In the window Interfaces click the <i>Bluetooth</i> tab.
		Click Add device
		The message appears: Switch on the Mobil-O- Graph [®] and change to PAIr mode.
2)	► Switch on the Mobil-O-Graph®	
	Change to PAIr mode:	
	► Hold down and press .	
	► Press until PAIr flashes on the display.	
	► Press ②.	
	PAIr stops flashing and the buzzer sounds.	
3)		► Click OK
		After a moment, the serial number appears
		in the window, for example C00607.
		► Click the serial number.
		► Click Pairing
		The message appears: Pairing successful.
		► Click OK.
		The window Connection with device appears.
		► Click Save
4)	Buzzer sounds	
5)		The monitor appears in the window <i>Interfaces</i> in the <i>Bluetooth</i> tab.
		► Click Save
6)	► Switch off the Mobil-O-Graph®	

The Bluetooth interface between the Mobil-O-Graph $^{\otimes}$ and the HMS-CS program is now configured. The software will detect the presence of the Mobil-O-Graph $^{\otimes}$ as soon as the recorder is placed in Bluetooth communications mode, denoted by "bt" on the recorder display.

Preparing the Mobil-O-Graph® for 24-hour monitoring

Starting situation:

- Mobil-O-Graph® is switched off,
- ■PC is switched on,
- Mobil-O-Graph[®] interface recognises HMS CS.

Step	Mobil-O-Graph [®]	PC
1)	► Switch on the Mobil-O-Graph [®]	
2)		 Start HMS CS. The active Bluetooth connection is shown in the Toolbar. Display the patient (see 4.6.1, Entering new patient and 4.6.2, Selecting existing patient)
3)	 ▶ Hold down and press . ▶ bt flashes on the display. ▶ Press . ▶ bt stops flashing and the buzzer sounds. 	
4)		The window Action of device appears.
5)	Buzzer sounds twice.	
6)		Click Prepare device Caution: If battery voltage is insufficient for 24-hour monitoring, a message will appear. Please note this information! The window Prepare monitor appears. Set the protocol for 24-hour monitoring (see 4.8.1, Setting the measurement protocol). Click Send Patient ID Click Send and activate. Click Close Click Close
7)	Buzzer sounds.	
	First, bt end and then the time appears on the display.	
8)		► In the toolbar, click► The program quits.

Begin 24-hour monitoring

Starting situation:

■ Mobil-O-Graph[®] is switched on.

Step	Mobil-O-Graph [®]	PC
1)	Put the monitor on the patient (put on the cuff and connect it to the recorder).	
	► Press for a manual measurement, to ensure that the monitor works as it should.	
	➤ Wait for the first, manual measurement.	
	If everything is in order, the patient can leave.	
	A successful measurement is necessary to activate the protocol!	

Read out measurements from 24-hour monitoring from Mobil-O-Graph $^{\otimes}$ via Bluetooth Starting situation:

- Mobil-O-Graph® is switched on,
- ■PC is switched on,
- Mobil-O-Graph® interface recognises HMS CS.

Step	Mobil-O-Graph [®]	PC
1)		The active Bluetooth connection is shown in the Toolbar. The window Action of device appears.
2)	 ► Take the monitor off the patient (take off the cuff and disconnect the recorder) ► Hold down nd press . ► bt flashes on the display. ► Press . ► bt stops flashing and the buzzer sounds. 	The window years, or device appears.
3)	Buzzer sounds twice.	
4)		The question appears: Assign measurements to patient with ID number xxx? Click After data transmission the window Measurement series appears. If necessary, change the times for the daytime and night intervals. Click The question appears: Assign measurements to patient with ID number xxx? Click The transmitted measurements are displayed as a Table of measurements.
4)	Buzzer sounds. First bt end , and then the time appear on the display. Market Switch off the Mobil-O-Graph®.	

For further analysis of measurement series see 4.11, Analysing measurements.

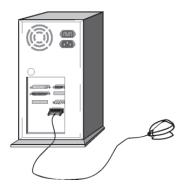
4.7.3 Connection via infrared (IR)

The IR-Med infrared interface enables wireless data transmission between the Mobil-O-Graph® monitor and the PC. The IR-Med infrared interface is connected to the PC by cable:

- via serial interface (COM1,2...) or
- via USB interface.



IR-Med infrared interface (right) with serial interface (left)



Connecting the serial interface to the PC

When using the Mobil-O-Graph® monitor with the *IR-Med* infrared interface, follow these steps:

- Connect the monitor to the PC,
- Configure the monitor in HMS CS
- Set the monitor for the patient using HMS CS,
- Test the monitor and put it on the patient.

After 24-hour monitoring

- Take the monitor off the patient (take off the cuff and disconnect the recorder),
- Read out measurements from monitor and save them in HMS CS under patient information.

Connect PC to Mobil-O-Graph® via IR-Med infrared interface

Step	Mobil-O-Graph [®]	PC
1)	► Switch off the Mobil-O-Graph®	
2)	Establish a connection between Mobil-O-Graph® and PC a) via serial interface (COM1,2) with cable or combi cable	
		► Switch off the PC
		► Connect the cable to the serial interface (COM1,2)
		► Switch on the PC.
	b) via USB interface	
		► Connect the cable to a USB port.
3)	➤ Point the Infrared interface of the Mobil-O- Graph® towards the <i>IR-Med</i> infrared interface at a distance of 10-15 cm.	
4)	► Switch on the Mobil-O-Graph®	
	Change to co mode:	
	► Hold down and press .	
	▶ Press until co flashes on the display.	
	▶ Press ♣.	
	co stops flashing and the buzzer sounds.	

Configuring interface between Mobil-O-Graph® and HMS CS

Starting situation:

- Monitor is connected to the PC,
- Mobil-O-Graph[®] is switched on,
- ■PC is switched on.

Step	Mobil-O-Graph [®]	РС	
1)		•	Start HMS CS.
			If the program is set up for this, the window Patient list will appear (see 4.12.7, <i>Extras</i>). In this case, select a patient (see 4.6.2, <i>Selecting existing patient</i>)
		•	In the menu bar, click Settings and then Interfaces .
		•	In the window Interfaces, click the Serial/IR/ USB tab.
		•	Set COM1,2 as the interface (see 4.12.4, Interfaces)

Preparing the Mobil-O-Graph® for 24-hour monitoring

Starting situation:

- Monitor is connected to the PC,
- Mobil-O-Graph® is switched on,
- ■PC is switched on,
- Mobil-O-Graph[®] interface recognises HMS CS.

Step	Mobil-O-Graph [®]	PC
1)		► Start HMS CS.
		▶ Display the patient (see 4.6.1, Entering new patient and 4.6.2, Selecting existing patient)
		► In the toolbar, click
		Caution: If battery voltage is insufficient for 24-hour monitoring, a message will appear. Please note this information!
		The window Prepare monitor appears.
		► Set the protocol for 24-hour monitoring (see 4.8.1, Setting the measurement protocol)
		► Click Set clock of device
		► Click Send Patient ID
		Click Send and activate.
		► Click Close
		► In the toolbar, click
		The program quits.
2)	► Switch off the Mobil-O-Graph®	

Begin 24-hour monitoring

Starting situation:

■ The monitor should be disconnected from the PC.

Step	Mobil-O-Graph [®]	PC
1)	Put the monitor on the patient (put on the cuff and connect it to the recorder).	
	► Switch on the Mobil-O-Graph [®] .	
2)	Press for a manual measurement, to ensure that the monitor works as it should.	
	► Wait for the first, manual measurement.	
	If everything is in order, the patient can leave.	
	A successful measurement is necessary to activate the protocol!	

After 24-hour monitoring session, connect PC to Mobil-O-Graph® via IR-Med infrared interface

After 24-hour monitoring session, transmit data from the monitor to HMS CS.

Starting situation:

- Mobil-O-Graph[®] is on the patient's arm and is switched on.
- ■PC is connected to IR-Med infrared interface.

Step	Mobil-O-Graph®	PC
1)	► Switch off the Mobil-O-Graph [®] .	
	► Take the monitor off the patient (take off the cuff and disconnect the recorder).	
2)	Point the Infrared interface of the Mobil-O- Graph [®] towards the <i>IR-Med</i> infrared interface at a distance of 10-15 cm.	
3)	► Switch on the Mobil-O-Graph [®] .	
	Change to co mode:	
	► Hold down and press .	
	▶ Press until co flashes on the display.	
	▶ Press €.	
	co stops flashing and the buzzer sounds.	

Read out measurements from 24-hour monitoring session from Mobil-O-Graph®

Starting situation:

- Monitor is connected to the PC,
- Mobil-O-Graph® is switched on,
- PC is switched on,
- Mobil-O-Graph® interface recognises HMS CS.

Step	Mobil-O-Graph®	PC
1)		► Start HMS CS.
		If the program is set up for this, the window Patient list will appear (see 4.12.7, Extras). In this case, select a patient(see 4.6.2, Selecting existing patient)
		► In the toolbar, click
		The question appears: Assign measurements to patient with ID number xxx?
		► Click Yes
		After data transmission, the window Measurement series appears
		If necessary, change the times for the daytime and night intervals.
		► Click Save
		The question appears: Delete patient ID and measurements from the recorder?
		► Click Yes
		The transmitted measurements are displayed as a Table of measurements.
2)	► Switch off the Mobil-O-Graph [®] .	

For further analysis of the measurement series see 4.11, Analysing measurements.

4.8 Preparing the monitor

Before monitoring a patient, send via HMS CS information about the planned monitoring to the monitor.

Starting situation:

- Monitor is connected to the PC,
- Monitor is switched on,
- PC is switched on and HMS CS is open,
- HMS CS recognises interface for monitor.

See 4.7, Using the Mobil-O-Graph® and 4.10, Using the Stabil-O-Graph® (optional).

Depending on the monitor, it will run through the following steps:

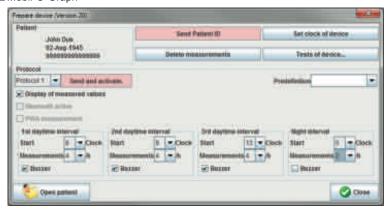
- Mobil-O-Graph®
- Set the measurement protocol, see 4.8.1, Setting the measurement protocol
- Set the monitor's clock, see 4.8.2, Setting the monitor's clock
- Import a patient ID, see 4.8.3, Importing a patient ID
- Device testing, see 4.8.4, Testing the monitor
- Delete old measurements, see 4.8.5, Deleting old measurements
- Begin 24-hour monitoring, see 4.8.8, Starting 24-hour monitoring with the Mobil-O-Graph®.
- Stabil-O-Graph® (optional)
- Set reminder times, see 4.8.6, Setting reminder times
- Set the monitor's clock, see 4.8.2, Setting the monitor's clock
- Import a patient ID, see 4.8.3, Importing a patient ID
- Device testing, see 4.8.4, Testing the monitor
- Delete old measurements, see 4.8.5, Deleting old measurements
- Begin measurements, see 4.8.9, Starting measurements with the Stabil-O-Graph®.
- ▶ Display the required patient (see 4.6.2, Selecting existing patient).



► In the toolbar, click

The window *Prepare monitor* appears. Its content depends on the type of monitor.

■ Mobil-O-Graph®



■ Stabil-O-Graph® (optional)



4.8.1 Setting the measurement protocol

Note: only possible for Mobil-O-Graph®

Here you arrange how the 24-hour monitoring will be performed. There are eleven different protocols. Protocols 1 and 2 are user-definable..

Protocol 10 transmits each value automatically after measurement to your doctor's PC via the Bluetooth interface, or to a database via mobile communications such as a mobile phone or modem. You can use Protocol 10 for monitoring in practice, or for telemonitoring.

For practice monitoring you will need a Bluetooth interface on your PC. Steps 1-6 under 4.7.2 must be performed and the patient in question opened in the HMS CS.

If you are interested in telemonitoring or require further information regarding practice monitoring, you can obtain this from your specialist dealer or directly from IEM GmbH.

Protocol 11 activates the additional pulse wave analysis. The intervals for blood pressure monitoring and pulse wave analysis can be configured independently. A PWA will always precede measurement of blood pressure, however.

Selecting a protocol

- ▶ In the pop-up field *Protocol* click the protocol you require.
- ▶ In Protocol 1 or 2, set the timeframe (beginning of time interval) under daytime interval and night interval,
 - timeframe (beginning of time interval),
 - the number of measurements during this interval,
 - whether the measurement will be shown on the monitor (Display measurements),
 - and whether an acoustic signal (buzzer) will sound as the measurement starts.

Transmit protocol

- Click Send and activate.
- ► Confirm with Yes

4.8.2 Setting the monitor's clock

Import the time on the PC into the monitor.



► Confirm with Yes

The monitor shows the imported time.

4.8.3 Importing a patient ID

You can save the Patient ID of the selected patient in the monitor. Later, when you import the 24-hour measurements, HMS CS will automatically recognise the patient.



Confirm with

4.8.4 Testing the monitor

You can ensure that the monitor is working properly.

Click Tests of device...

The window $\ensuremath{\textit{Device testing}}$ appears. Its content depends on the type of monitor.

■ Mobil-O-Graph®



■ Stabil-O-Graph® (optional)



- ► Click the function key in question.
- ► Confirm with <u>Yes</u>

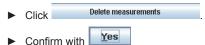
Complete testing

Click Close

4.8.5 Deleting old measurements

Measurements in the monitor are usually deleted after transmission to the PC. If however there are still "old" Measurements from a previous patient in the monitor, HMS CS will indicate this when preparing the monitor for a "new" patient.

To remove the "old" measurements from the monitor



4.8.6 Setting reminder times

Note: only possible for the Stabil-O-Graph®

Here you can arrange when and how the patient is reminded to measure BP.

Setting the time

▶ You decide the reminder time.

Read out reminder times from the monitor

► Click Read-out

The time and type of reminder are imported from the monitor and displayed.

Setting the type of reminder

The monitor is able to remind the patient to measure BP in two ways:

- By flashing light
- By flashing light and buzzer.

Activating flashing light and buzzer:

► Click the option button Active.

A tick appears.

Send reminder times to the monitor

- Send
- <u>Y</u>es Confirm with

4.8.7 **Ending device preparation**

Close

The window Prepare monitor disappears.

▶ Disconnect the physical connection between monitor and PC.

4.8.8 Starting 24-hour monitoring with the Mobil-O-Graph®

After completion of device preparation in HMS CS, you can start monitoring the patient.

Starting situation:

- The monitor should be disconnected from the PC.
- ▶ Put the monitor on the patient (put on the cuff and connect it to the recorder).
- Switch on the monitor.

Ensure that the monitor works as it should.

- Press for a *manual* measurement.
- Wait for the first, automatic measurement.

If everything is in order, the patient can leave.

4.8.9 Starting measurement with the Stabil-O-Graph®

After completion of device preparation in HMS CS, you can start monitoring the patient.

Starting situation:

- The monitor should be disconnected from the PC.
- ▶ Put the monitor on the patient (put on the cuff and connect it to the recorder).

Ensure that the monitor works as it should.

Press any key.

The time and date are displayed.

for a measurement, to ensure that the monitor works as it should.

If everything is in order, the patient can leave.

Reading out measurements from the monitor

You can transmit data from the monitor to HMS CS.

Depending on the monitor, it will run through the following steps:

- Mobil-O-Graph[®]
 - End 24-hour monitoring, see 4.9.1, Ending 24-hour monitoring with the Mobil-O-Graph®
 - Connect HMS CS to monitor, see 4.9.2, Connecting HMS CS to the Mobil-O-Graph®
 - Import measurements from monitor, see 4.9.4, Importing measurements from monitor into HMS CS.
- Stabil-O-Graph® (optional)
 - Connect HMS CS to monitor, see 4.9.3, Connecting HMS CS to the Stabil-O-Graph®
 - Import measurements from monitor, see 4.9.4, Importing measurements from monitor into HMS CS.

4.9.1 Ending 24-hour monitoring with the Mobil-O-Graph®

Starting situation:

- Monitor is on the patient's arm and is switched on.
- Switch the monitor off.
- Take off the monitor from the patient.

4.9.2 Connecting HMS CS to the Mobil-O-Graph®

- ► Connect the switched-off monitor with the PC.
- Start HMS CS.

4.9.3 Connecting HMS CS to the Stabil-O-Graph®

- ► Connect the switched-off monitor with the PC.
- Start HMS CS.

4.9.4 Importing measurements from monitor into HMS CS

► Start HMS CS.

If the program is set up for this, the window Patient list will appear (see 4.12.7, Extras). In this case, select a patient (see 4.6.2, Selecting existing patient)

▶ If using the IR interface or cable in the toolbar, click







HMS CS checks whether the Patient ID is in the monitor.

If yes	If not
The question appears: Assign measurements to patient with ID number xxx?	Select the required patient (see 4.6.2, Selecting existing patient).
► Click Yes	

The measurements are imported into HMS CS and saved under that patient.

The question appears: Delete Patient ID and measurements from the recorder?

Note: It is normally sensible to delete these details from the monitor. When preparing the monitor for a "new" patient, HMS CS indicates whether "old" measurements are still in the monitor.

If yes	If not	
► Click Yes	► Click No	

The window Measurement series appears.



- ▶ If necessary, change the times of daytime and night intervals.
- ► Type in a report.
- Click Save

The measurements transmitted are displayed as a table of measurements (see 4.11.1, Table of measurements).

4.9.5 Exporting measurements

You can save measurements from a 24-hour monitoring session, which you have imported from a monitor into HMS CS and analysed, in a file. Using this file you can, for example, import these data into your practice's system.

- ▶ Display the required patient (see 4.6.2, Selecting existing patient).
- ▶ In the control window, click the *Measurements tab*.

The Measurements tab contains, on the left, a list of the monitoring sessions already performed.



- Click the monitoring session with the measurements to be exported.
- ▶ Click on **test series** in the menu bar and then on **export** (Excel, XML or GDT).
- Set the directory and name for the file.
- Click Save

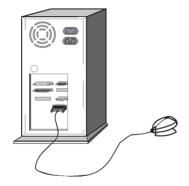
4.10 Using the Stabil-O-Graph $^{\circledR}$ (optional)

The IR-Med infrared interface enables wireless data transmission between the Stabil-O-Graph NG[®] monitor and the PC. The *IR-Med* infrared interface is connected to the PC by cable:

- via serial interface (COM1,2...) or
- via USB interface.



IR-Med infrared interface (right) with serial interface (left)



Connecting the serial interface to the PC

When using the Stabil-O-Graph NG® monitor with the IR-Med infrared interface, follow these steps:

- Connect the monitor to the PC,
- Configure the monitor in HMS CS
- Set the monitor for the patient using HMS CS,
- Test the monitor and put it on the patient.

After monitoring

- Take the monitor off the patient and connect it to the PC,
- Read out measurements from monitor and save them in HMS CS under patient information.

Connect PC to Stabil-O-Graph®

Step	Stabil-O-Graph [®]	PC
1)		➤ Switch off the PC
2)	Establish a connection between Stabil-O-Graph® ar	nd PC
	a) via serial interface (COM1,2) with cable or con	mbi cable
		► Connect the cable to the serial interface (COM1,2).
	b) via USB interface	
		► Connect the cable to a USB port.
3)	➤ Point the Infrared interface of the Mobil-O-Graph [®] towards the <i>IR-Med</i> infrared interface at a distance of 10-15 cm.	STABIL © GRAPH CO STORY STABIL OF GRAPH CO STA
4)	Change to co mode:	
	► Hold down and press co appears on the display.	
5)		► Switch on the PC

Configuring interface between Stabil-O-Graph® and HMS CS

Starting situation:

- Monitor is connected to the PC,
- Stabil-O-Graph® is switched on,
- ■PC is switched on.

Step	Stabil-O-Graph [®]	PC	
1)		► Start HMS CS.	
		If the program is set up for this, the window Patient list will appear (see 4.12.7, Extras). In this case, select a patient (see 4.6.2, Selecting existing patient)	
		► In the menu bar, click Settings and then Interfaces .	
		► In the window Interfaces, click the Serial/IR/USB tab.	/
		► Set COM1,2 as the interface (see 4.12.4, <i>Interfaces</i>)	

Prepare Stabil-O-Graph® for monitoring

Starting situation:

- Monitor is connected to the PC,
- Stabil-O-Graph® is switched on,
- ■PC is switched on,
- HMS CS recognises the interface for Stabil-O-Graph[®].

Step	Stabil-O-Graph [®]	PC
1)		► Start HMS CS.
		▶ Display the patient (see 4.6.1, Entering new patient and 4.6.2, Selecting existing patient)
		► In the toolbar, click
		Caution: If battery voltage is insufficient for 24-hour monitoring, a message will appear. Please note this information!
		The window Prepare monitor appears.
		➤ Set the Reminder times (see 4.8.6, Setting reminder times).
		► Click Set clock of device
		► Click Send Patient ID
		► Click Send
		► Click Close
		► In the toolbar, click
		The program quits.

Start measurement

Starting situation:

■ The monitor should be disconnected from the PC.

Step	Stabil-O-Graph [®]	PC
1)	Put the monitor on the patient (put on the cuff and connect it to the recorder).	
2)	► Press any key.	
	The time and date are displayed.	
	Press for a measurement, to ensure that the monitor works as it should. If everything is in order, the patient can leave.	

At the patient's next visit, connect PC to the Stabil-O-Graph® via IR-Med infrared interface

You can transmit the data from the monitor to HMS CS.

Starting situation:

- Stabil-O-Graph® is switched on.
- ■PC is connected to IR-Med infrared interface.

Step	Stabil-O-Graph [®]	PC
1)		► Switch on the PC
2)	➤ Point the Infrared interface of the Mobil-O-Graph® towards the <i>IR-Med</i> infrared interface at a distance of 10-15 cm.	STABLE GRAPH CO STORY STORY MENU STORY
3)	Change to co mode:	
	Hold down and press co appears on the display.	

Read out measurements from Stabil-O-Graph®

Starting situation:

- Monitor is connected to the PC,
- $\blacksquare\operatorname{Stabil\text{-}O\text{-}Graph}^{\circledR}$ is switched on,
- PC is switched on,
- HMS CS recognises the interface for Stabil-O-Graph[®].

Step	Stabil-O-Graph [®]	PC
1)		► Start HMS CS.
		If the program is set up for this, the window Patient list will appear (see 4.12.7, Extras). In this case, select a patient (see 4.6.2, Selecting existing patient)
		► In the toolbar, click
		The question appears: Assign measurements to patient with ID number xxx?
		► Click Yes
		After data transmission, the window Measurement series appears.
		If necessary, change the times for the daytime and night intervals.
		► Click Sawe
		The question appears: Delete patient ID and measurements from the recorder?
		► Click Yes
		The exported measurements transmitted are displayed as a table of measurements.

For further analysis of the measurement series see 4.11, Analysing measurements.

4.11 Analysing measurements

Starting situation: You have already read out measurements from the recorder and saved them in HMS CS (see 4.9, Reading out measurements from the recorder).

The following analyses and functions are available for analysing measurements:

Tab header	Analysis
	Table of measurements, see 4.11.1, Table of measurements
	BP profile, see 4.11.2, <i>BP profile</i>
FIII	Self-measurements, see 4.11.3, Self-measurements
	Correlation, see 4.11.4, Correlation
•	Values above limit, see 4.11.5, Values above limit
	Frequency distributions, see 4.11.6, Frequency distributions
MIN ©	Report, see 4.11.7, Report
	Hourly mean values, see 4.11.8, Hourly mean values
	Changes in blood pressure, see 4.11.9, Changes in blood pressure
	Printing Patient information and analyses of measurements, see 4.11.10, <i>Printing</i>
	24h-PWA, see 4.11.12, 24h-PWA
ETIT	Bar chart (PWA),see 4.11.13, Bar chart (PWA)
	Patient report,see 4.11.14, Patient report (Day average)

Tip: If your mouse pointer hovers over a tab, a brief explanatory text will appear (Tooltip).

- ▶ Display the patient you want to see (see 4.6.2, Selecting existing patient).
- In the control window, click the Measurements tab.

The Measurements tab contains, on the left, a list of the monitoring sessions already performed.



Click a monitoring session.

The respective table of measurements is displayed.

The highlighted values are measurements that lie outside the defined limits (see 4.12, Setting standard values for HMS CS).

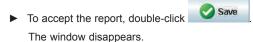
► To display further analyses, click the required tab header.

Enter report on measurement series

▶ Double-click the monitoring session.

The window Measurement series appears.

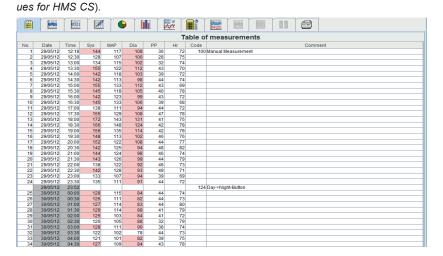
► Type in your report.



4.11.1 Table of measurements

The table of measurements lists all measurements in a measurements series as a table.

To display the table of measurements, click on the tab The highlighted values are measurements that lie outside the defined limits (see 4.12, Setting standard val-



Tip: If your mouse pointer hovers over the table header, a brief explanatory text will appear (e.g. 24h BP monitor, automatic measurement).

Commenting on a measurement

- ► Click the column Commentary in the required row.
- Type in your comment.
- Press the return key.

Excluding a measurement

If one measurement is a complete outlier and would therefore falsify a representative 24-hour analysis, you can exclude it:

Click the column No. in the required row.

The number of the measurement disappears and that value is now excluded from statistical analyses from

Note: To include the measurement again, click the number again.

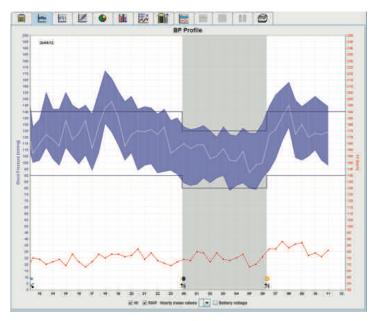
Printing table of measurements

Click on the tab (see 4.11.10, Printing).

4.11.2 Blood Pressure Profile (trend)

The profile shows a diagram of the following values as a function of time:

- systolic values
- mean values
- diastolic values
- heart rate.
- To display the table of measurements, click on the tab



The left-hand y-axis with the units mmHg applies to systolic, diastolic and mean values (BP values).

The right-hand y-axis with the units 1/min applies to heart rate.

The x-axis applies to time. The four daily intervals are highlighted. Day counts all three daytime intervals together. "M" signifies manual measurements

You can see the upper BP limits (systolic, diastolic) as horizontal set-point curves.

Note: You can set these values in the Patient information tab in the BP limits field.

Show and hide mean values

► Click the option button *MAP*.

Show and hide hourly mean values

▶ In the pop-up field *Hourly mean values*, click the required number of hours.

Show or hide heart rate

► Click the option button Heart rate.

Display single measurements

▶ In the diagram, click the required time point.

A vertical line appears and the measurements are displayed in a window.

Tip: To see neighbouring measurements, move the mouse over the diagram. The vertical line follows the mouse movement and the respective values are displayed.

► Click again to turn off this display.

Zooming in (increasing the size of the diagram)

▶ Use the mouse to click in the diagram, hold the mouse button down and drag open the section from left to right.

Zooming out (return diagram to original size)

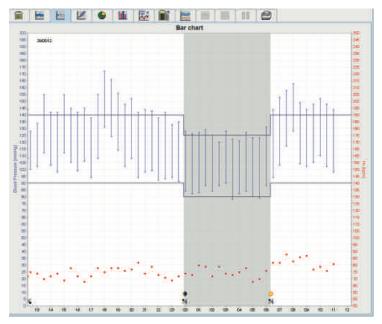
▶ Use the mouse to click in the diagram, hold the mouse button down and drag open the section from *right to left*.

4.11.3 Profile

In this profile view the following values of the test series will be displayed graphically as a function of time in a bar diagram:

- systolic values
- median Values
- diastolic values
- heart rate
- ➤ To display self-measurements, click on the tab





The left-hand y-axis with the units mmHg applies to systolic, diastolic and mean values (BP values).

The right-hand y-axis with the units 1/min applies to heart rate.

The x-axis applies to time. The four daily intervals are highlighted. Day counts all three daytime intervals together. "M" signifies manual measurements.

You can see the upper BP limits (systolic, diastolic) as horizontal set-point curves.

Note: You can set these values in the Patient information tab in the BP limits field.

Zooming in (increasing the size of the diagram)

▶ Use the mouse to click in the diagram, hold the mouse button down and drag open the section from *left to right*.

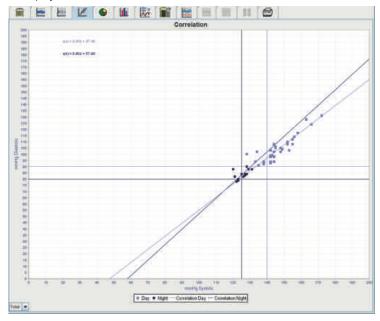
Zooming out (return diagram to original size)

▶ Use the mouse to click in the diagram, hold the mouse button down and drag open the section from right to left.

4.11.4 Correlation

This diagram shows the correlation of diastolic to systolic blood pressure. Each dot corresponds to one measurement.

► To display the correlation, click on the tab



The y-axis applies to diastolic values. the x-axis applies to systolic values.

You can see the BP limits as horizontal (systolic) and vertical (diastolic) set-point curves.

Note: You can set BP limits in the Patient information tab in the BP limits field.

Show or hide daytime/night measurements

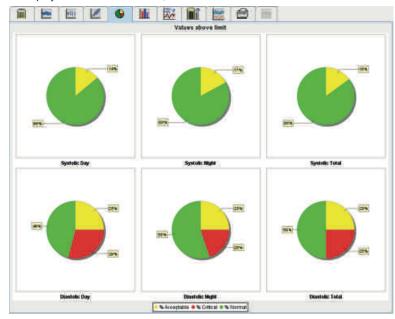
▶ In the pop-up field, click below left on the required diagram (total, day, night).

4.11.5 Values above limit

The values of one measurement series are analysed according to the BP limits set. Various pie charts show the percentages of acceptable, too high and normal measurements.

Note: You can set BP limits on the Patient information tab in the BP limits field.

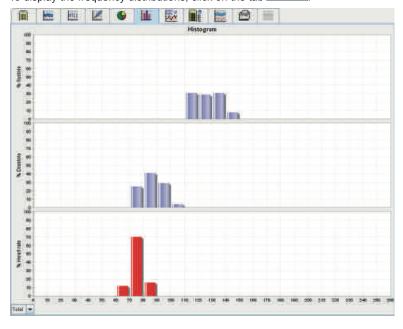
► To display the values above limit, click on the tab



4.11.6 Frequency distributions

The frequency distributions of systolic and diastolic measurements and heart rate are shown as histograms. A bar chart contains the percentages of 10 units, i.e. 80-89, 90-99 etc.

► To display the frequency distributions, click on the tab



Selecting measurements for calculation

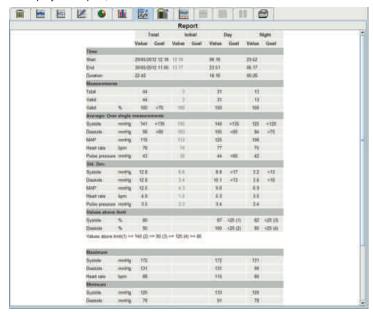
▶ In the pop-up field, click below left on the required period for calculation (total, day, night). In the displays for day and for night, vertical lines indicate the BP limits.

Note: You can set BP limits on the Patient information tab in the BP limits field.

4.11.7 Report

The report contains important statistical statements on systolic and diastolic blood pressure. The values are shown for day and night, respectively.

To display the report, click on the tab



Directly below Day and Night are average values and the scatter (empirical standard deviation) of the meas-

Below Systolic and Diastolic you will see the frequency distribution of the measurements. The frequency distribution shows how many measurements out of all the valid measurements lie above a particular value. The BP limit set for this patient is used as a starting value.

You can set the BP limits on the Patient information tab in the BP limits field.

The result report can also be displayed in tabular form. Click on analysis in the settings menu and check the tabular display box

Below Day/Night lowering you can see the percentage lowering of the BP mean values (= average values) between day and night.

Changing the limits for frequency distribution

▶ In the list field, click the arrows beside **Values** >= to change the limit. The newly calculated values are shown automatically.

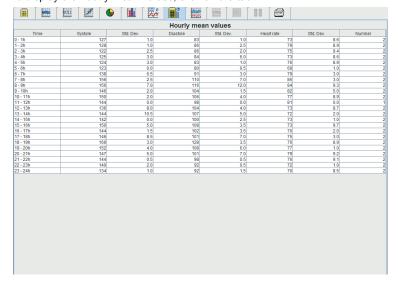
Printing report

Click on the tab (see 4.11.10, Printing).

4.11.8 Hourly mean values

This analysis lists all hourly mean values for blood pressure and pulse as a table.

► To display the hourly mean values, click on the tab



Change basis for calculating hourly mean values

▶ In the pop-up field *Basic mean value (h)*, click the required number of hours (1, 2, 3, 4, 6, 8).

The intervals in the left-hand column are displayed accordingly. The hourly mean values are recalculated.

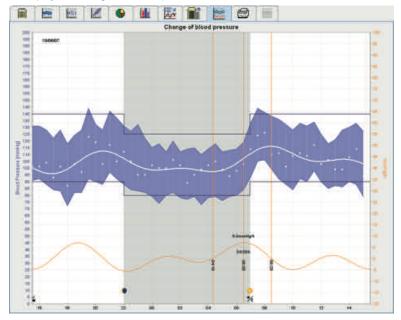
Printing hourly mean values

► Click on the tab (see 4.11.10, *Printing*).

4.11.9 Changes in blood pressure

You can use this analysis to monitor the morning rise in blood pressure. The following values in the measurement series are displayed graphically as a function of time:

- systolic values
- mean values
- diastolic values
- heart rate.
- ► To display the changes in blood pressure, click on the tab



The left-hand y-axis with the units mmHg applies to systolic, diastolic and mean values (BP values).

The right-hand y-axis with the units mmHg/h applies to blood pressure change.

The x-axis applies to time. The intervals for morning rise in blood pressure are highlighted.

The lower, flattened curve shows the course of blood pressure. It transforms blood pressure data in the frequency range of mean arterial pressure through Fourier analysis. The outliers are neglected, giving the curve shown after inverse Fourier transformation. It shows the positive changes in blood pressure (mmHg per hour) for times of rise in BP, and the negative change for times of BP lowering. The red, vertical lines mark the beginning and end (=duration) of the early-morning rise and the time and magnitude of the maximum rise. The upper BP limits (systolic, diastolic) are shown as horizontal set-point curves.

Note: You can set these values in the Patient information tab in the BP limits field.

Display single measurements

▶ In the diagram, click the required time point.

A vertical line appears and the measurements are displayed in a window.

Tip: To see neighbouring measurements, move the mouse over the diagram. The vertical line follows the mouse movement and the respective values are displayed.

Click again to turn off this display.

Zooming in (increasing the size of the diagram)

▶ Use the mouse to click in the diagram, hold the mouse button down and drag open the section from left to right.

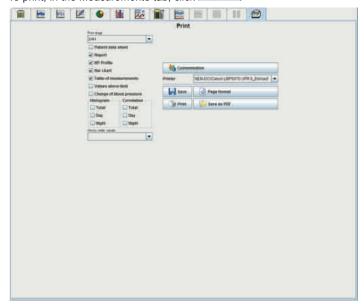
Zooming out (return diagram to original size)

▶ Use the mouse to click in the diagram, hold the mouse button down and drag open the section from right to left.

4.11.10 Printing

The Print function enables you to print the analyses you require.

► To print, in the *Measurements* tab, click



► Click the analyses to be printed.



The window Print appears.

4.11.11 Comparing several measurement series

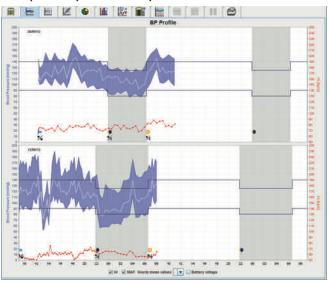
If there are at least two measurement series stored for a patient, you can compare them. Depending on the analysis,

- diagrams of the individual measurement series are shown one below the other,
- or the values are cumulated and shown as a graph.

Selecting and comparing several measurement series

- ► Click the first measurement.
 - The measurement series is highlighted.
- lacktriangle Hold down the Ctrl-key and then click on the further measurement series you require.
 - These measurement series are then also highlighted.
- ► Click the header tab of the required analysis.

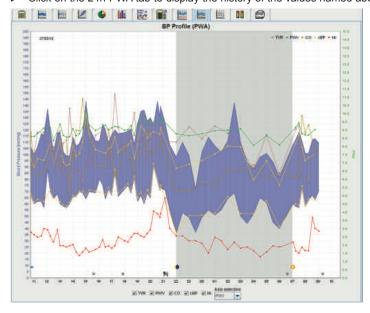
Example: Comparison of BP profile from two measurements



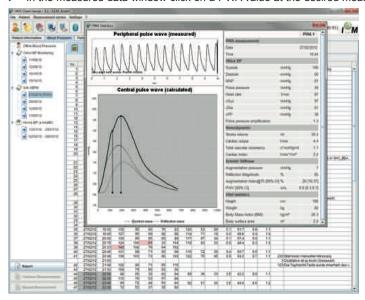
4.11.12 24h-PWA

In this analysis, the PWA history is displayed over a 24h-period at preset protocol 11. In addition to blood pressure and pulse, the following parameters are displayed as a time series:

- Central blood pressure
- Alx@75 [90%CI]
- Cardiac Output [CO]
- Total vascular resistance
- Click on the 24h-PWA tab to display the history of the values named above.



- ▶ Click on the tab measured data to display a single PWA.
- ▶ In the measured data window click on a PWA value at the desired measuring.



The pop-up window displays the PWA just like a PWA conducted at the doctor's practice.

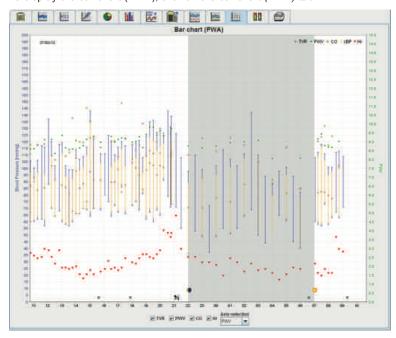
4.11.13 Bar chart (PWA)

In the bar chart for PWA (pulse wave analysis) measurements with protocol 10 or protocol 11, the peripheral and central blood pressure readings are shown as a function of time. The bar chart (PWA) directly compares these blood pressure readings. Peripheral blood pressure readings are shown in blue, while central blood pressure readings are shown in yellow.

The following measurements can be shown in the bar chart (PWA) as an option: TVR (total vascular resistance), PWV (pulse wave velocity), cardiac output and heart rate.

The bar chart (PWA) cannot be selected for non-PWA measurements.

To display the bar chart (PWA), click on the bar chart (PWA) tab



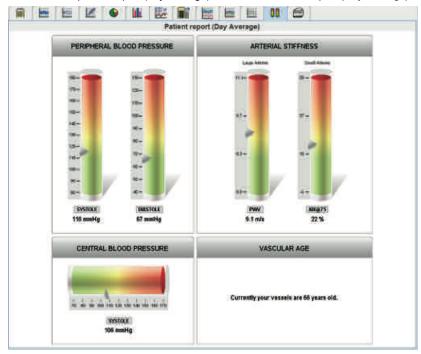
4.11.14 Patient report (Day Average)

In the case of PWA measurements as part of 24h ABPM values, the patient report displays the average of selected haemodynamic information determined during the measurement period.

In the case of PWA measurements in the doctor's office, the patient report displays haemodynamic information determined from the single measurement.

To access the patient report (day average), click on the Patient report (Day Average) tab





The Patient report (Day Average) tab is divided into four areas:

Peripheral blood pressure:

The peripheral blood pressure area displays the peripheral systolic and peripheral diastolic blood pressure measured.

Central blood pressure:

The central blood pressure area displays the central systolic blood pressure calculated.

Arterial stiffness:

The arterial stiffness area displays the PWV (pulse wave velocity) measured for large vessels and the augmentation index at a heart rate of 75 1/min (Alx@75) in the case of small vessels.

Vascular age:

The vascular age area shows the vascular age of the patient determined from the haemodynamic information. The vascular age display can be set in the Hypertension Management Software settings.

Central blood pressure and calibration:

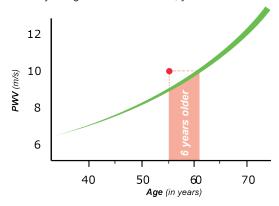
Currently, calibration is used when calculating the central aortic systolic blood pressure. As a rule, peripheral systolic blood pressure is used. Calibration can also be used according to the MAP measured (mean arterial pressure, corresponds to the maximum oscillometric amplitude).

Scientific findings published recently prove for the first time that calibration according to the measured MAP is more predictive than other comparable methods.

To use the MAP-C2 calibration for calculating the aortic central systolic blood pressure, in the menu bar, click on Settings -> Extras and enable MAP-C2-calibration for PWA.

Further information on the vascular age display:

The vascular age of a patient is calculated based on the pulse wave velocity measured. In addition to the normal age-related development of arterial stiffness in healthy people (green curve), measured in metres per second (m/s), there are also people who do not fit the normal pattern (red dot). If you follow the measurement horizontally along to the normal curve, you can derive the vascular age of a patient.



The vascular age display can be changed in the Hypertension Management Software settings. Here, you can set the standard procedures for:

- · Absolute or relative vascular age
- · Patient report display with or without smiley

Through combinations of these settings, you have the following options for displaying the vascular age in the patient report:

- Option 1: Depiction with smiley, vascular age: relative
- Option 2: Depiction with smiley, vascular age: absolute
- Option 3: Depiction without smiley, vascular age: relative
- Option 4: Depiction without smiley, vascular age: absolute

4.12 e-health

The HMS CS supports the **e-health service data base** (telemedicine) provided by I.E.M. GmbH. Using this service you can setup your own virtual patient clinic. Vital values measured by the patient himself are transferred via mobile radio to a server and can be synchronized with the HMS CS at any time.

Using the client-server solution you can:

- Create patients for e-health on the e-health server.
- Synchronize the data of selected patients with the e-health server.
- Request telemetrically surveyed measured values
- Save measured practice values on the server and enable access to them for your colleagues

4.12.1 Activate e-health service

- ► Click on settings in the menu bar and then on e-health service.
- ► The e-health service window appears



- ► Check the active box and thereby activate the e-health service.
- ▶ Enter the user name and password, which you received from I.E.M. GmbH or your retailer.
- ► Click on export settings.
- ► The export settings window appears.



In the **export settings** window you can specify which data will be transferred to the e-health server and if these will be anonymized.

If the anonymize box is checked, then only the patient ID is used

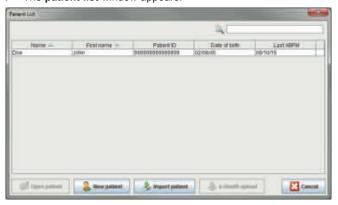
► Click on save.

The window disappears

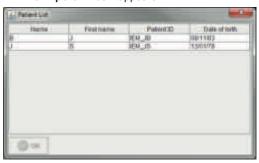
4.12.2 Import Patients from e-health server



► The patient list window appears.



- Click on import patient.
- ► The **import** window appears.

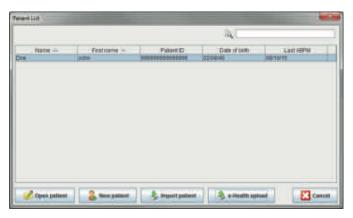


- ▶ Check the patients, which you want to import from the e-health server to your HMS CS.
- ► Click on import and the patients highlighted in blue will be imported into your HMS CS; including existing test series.

4.12.3 Export Patients to e-health Server



► The patient list window appears.



- Click on export patient
- The export window appears



Click on yes

Already opened patients can also be exported using the symbol.





After the import or export of patients, the patients authorized for e-health are marked with a small patient list and thereby authorized for synchronization with the e-health server.

If you open such a patient, all new telemetric measurements will be automatically polled from the e-health server.

If you want to reverse the clearance of a patient on the e-health server, click



4.13 Practice Monitoring

The practice monitoring should relieve the practice, increase therapy quality and improve patient comfort. The Mobil-O-Graph can be carried by the patient in the practice, e.g. in the waiting room, and the test series is transferred directly via Bluetooth to a practice computer. Each measurement is transferred wirelessly to the HMS CS and can be analyzed by the Doctor directly

You can use the practice monitoring for:

- intervention during high pressure crises.
- minimum invasive intervention (Warning: The system does not provide an alarm function!)

4.13.1 Prepare Mobil-O-Graph® for the practice monitoring

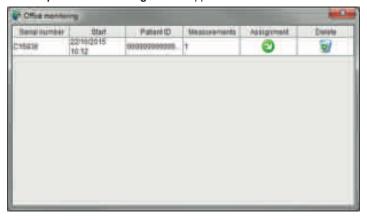
The Bluetooth interface of the Mobil-O-Graph is used for the practice monitoring. If you have never worked with the Bluetooth interface, then please follow the instructions under 4.7.2 Connection via Bluetooth® for the configuration of the interface.

- Select protocol 10 for the practice monitoring (see 4.8.1 specify measurement protocol).
- Choose the time interval 30, 20, 15, 12... measurements per hour.
- Attach the measuring device to the patient (fasten the cuff and connect to the device).
- To ensure that the device functions as desired, push for the start of a manual measurement. A successful measurement is a condition for the activation of the protocol!
- Wait for the first automatic measurement.

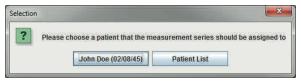
4.13.2 Assign received test series



- ▶ After the first measurement the Symbol appears in the symbol list. Click on this symbol.
- ► The practice monitoring window appears



- ► Click on assign
- ► The **selection** window appears



▶ Here you can assign the test series to the currently opened patient or to a patient from the patient list.

4.14 Pulse Wave Analysis (PWA)

The HMS CS has, in connection with the Mobil-O-Graph[®], in addition to the classic 24h blood pressure measurement also an integrated system for the pulse wave analysis (PWA). This function can be activated using a USB license dongle. The License dongle can be purchased at I.E.M. GmbH or your retailer.

Additionally, a Mobil-O-Graph® with integrated 24h-PWA is offered. This enhanced Mobil-O-Graph® provides a bigger memory and an integrated, unlimited license. This allows, for the first time, to record the history of a pulse wave parameter for 24 hours

The pulse wave analysis is based on the notion that the arterial blood pressure curve contains hemodynamic information that exceeds peripherally measured blood pressure. This is used to analyse all information regarding the central aortic pulse wave.

The following values are displayed:

- Central blood pressure
- Central pulse pressure
- Augmentation pressure
- Augmentation index
- Alx@75 [90% confidence interval]
- Cardiac Output [CO]
- Peripheral resistance
- Reflection co-efficient
- Pulse Wave Velocity [PWV]

4.14.1 Installation of the PWA at the doctor's practice

The PWA functionality is available for the Mobil-O-Graph® with the serial number 6000 upwards in connection with the HMS CS Version 2.0 and higher.

If you want to do pulse wave analyses you will need a USB dongle license. This dongle is simply plugged into a free USB port on your PC. If all USB ports on your PC are taken, you can purchase a USB Hub for the USB port extension at I.E.M GmbH or at your retailer. When you start a PWA measurement afterwards, the dongle is recognized and the measurement is authorized.

4.14.2 Carry out pulse wave analysis

The pulse wave analysis is in practice carried out via the Bluetooth interface or the IR interface of the Mobil-O-Graph®. If you have previously only worked with a cable interface, please follow the instructions in section 4.7.2 Connection via Bluetooth or 4.7.3 Connection via Infrared (IR) for the configuration of the interface.

- Attach the Mobil-O-Graph® cuff to the patient and connect the cuff to the device.
- Switch on the Mobil-O-Graph®.
- Select the patient in the HMS CS or create a new patient.

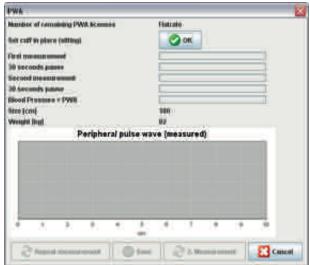
The PWA measurement is always assigned to the currently opened patient.

Caution: For the carrying out of the PWA the patient's age, size and weight must be entered into the HMS CS.

- Connect the Mobil-O-Graph to the HMS CS via Bluetooth or Infrared.
- PWA If you use Bluetooth, select in the appearing window to start the PWA measurement window
- If you use infrared, start the PWA measurement window with the



The following PWA measurement window appears:



- Click on OK to start the measurement.
- When all measurement steps of the PWA ran successfully please click on



4.14.3 Triple Pulse Wave Analysis

Triple PWA measurements refer to three individual PWA measures taken one after the other with short intervals in-between. This method is used to detect possible white coat hypertension in the doctor's office.

- Connect the Mobil-O-Graph to the HMS CS via Bluetooth.
- Triple PWA If you use Bluetooth, select in the appearing window to start the Triple-PWA measurement window.
- Click on **OK** to start the measurement.

After taking a Triple PWA measurement, a statistics window appears listing the three PWA measures taken so that you can compare them. The individual measurements are displayed in different colours.

Click Print to print the statistics.

After the statistics window has been confirmed with **OK**, the window itself cannot be retrieved. The individual PWA measurements then appear consecutively in the list of measurements already taken.

To take a Triple PWA measurement, you need three PWA licenses.

4.14.4 Activating the 24h-PWA

Recording a 24h-PWA requires the Mobil-O.Graph NG with integrated 24h-PWA as well as the HMS CS, version 4.0 or higher.

Upon the preparation of the device, choose protocol 11 to carry out the 24h-PWA. The entire preparation is carried out like a 24h-ABPM. See chapter 4.8 for more information.

Preparing the Mobil-O-Graph ® with integrated 24h-PWA with **protocol 11** starts a regular blood pressure measurement at the preset intervals. After measuring blood pressure, a PWA is carried out as well, by re-inflating the device and recording the pulse at the diastolic pressure.

The 24h-PWA measurement identifies patients suspected of having LVH (left ventricular hypertrophy) and correlates with the actual physiological aortic systolic blood pressure. Initial scientific evidence shows that predictions regarding mortality are significantly better suited if the **MAP-C2-calibration** is used.

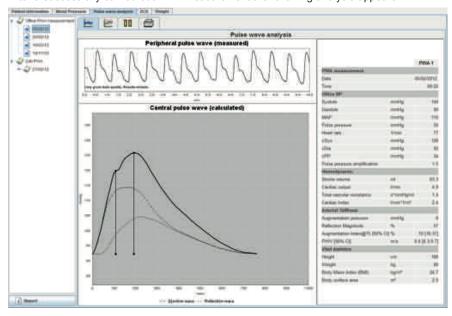
4.14.5 Reading and Analysing the 24h-PWA

Reading and analysing is carried out like a regular 24h-ABPM.

See chapter 4.9 "Reading Measured Values and Measuring Device" and 4.11.12 "24h-PWA".

4.14.6 Display of Pulse Wave Analysis

After a successfully carried out PWA measurement the following analysis appears



Out of 10 measured pulse waves, one filtered, average pulse wave is determined and the central aortal pulse wave is calculated with it.

The augmentation index (Alx) is always cited in the literature in dependence of sex, age and heart rate. For this reason a standardized display in accordance with these conditions is often used. First the augmentation index is standardized using an empiric determined regression [1] to 75 heart beats. This parameter is then described as Alx@75. If you analyse a representative cross-section of the population, as for example described in [2], you shall receive an age-dependent estimate for the Alx@75 plus the respective confidence interval. These relevant analyses have also shown that there is a significant difference for the average Alx@75 between men and women.

Based on research with a surveyed cross-section of the population of about 2,000 people, in the following figure average values and 90% confidence interval were determined. As with the already discussed analysis, an increase of the Alx until the 55th year can also be identified in the self-surveyed measurements. Afterwards, a plateau building up for both sexes follows. The level difference of the Alx between the sexes is about 8 to 10%. If the measured values exceed the sex- and age-specific interval, further examinations according to the European examination guidelines for hypertension [3] are recommended in order to detect the reason for the dysfunction.

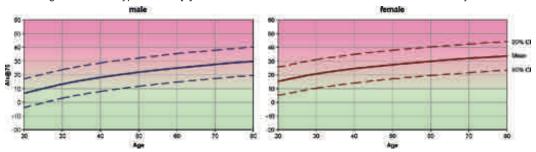


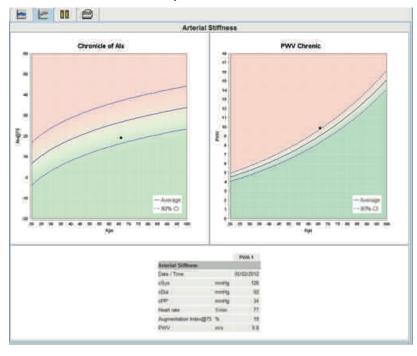
Figure 4.1: Average value and 90% confidence interval for the Alx@75

- 1) Wilkinson I.B. et al. *Heart Rate Dependency of Pulse Pressure Amplification and Arterial Stiffness*. American Journal of Hypertension 2002;15:24-30.
- Fantin F. et al. Is augmentation index a good measure of vascular stiffness in the elderly? Age and Ageing 2007; 36: 43-48.
- The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC). 2007 Guidelines for the management of arterial hypertension. European Heart Journal 2007; 28: 1462-1536.

4.14.7 Alx and PWV chronic

To retrieve the Alx and PWV history, click the Arterial stiffness tab





The Alx chronic shows the Alx@75 depending on age.

The PWV chronic shows the PWV depending on age.

Both diagrams show the average of the parameters for the respective age with the associated confidence interval.

The Alx@75 or PWV can be depicted in both diagrams only in patients aged 20 years or over if the quality of data of a PWA measurement is also adequate for the Alx@75 or PWV to be depicted.

If one of these criteria is not met, the following message appears in the diagrams:

- The data cannot be depicted due to: age
- · The data cannot be depicted due to: quality

4.15 GDT-Interface

The HMS CS offers the option to be integrated into a practice administration system via the GDT interface. After the integration into the practice software (see 4.14.8, GDT settings) and the start of the **HMS_GDT.EXE** in the program directory you will find a new symbol next to the IEM Logo in the upper right corner:



In this mode patient lists cannot be selected. The patient, who is transferred to the practice software, is active. The same will be, if known, loaded from the data base or a new entry created.

For known patients the existing test series can be reviewed or be requested directly from the practice software if the same is accordingly configured.

4.15.1 Transfer Analysis Reports to Practice Software

- ▶ Either close the HMS CS or set the HMS CS into the observation mode.
- You can enter the observation mode by clicking the symbol right next to the IEM Logo. The software is then minimized and waits for incoming GDT files in the background. As soon as a file is found, the software starts automatically with the patient.

4.16 Setting standard values for HMS CS

You can establish the following settings for the program:

- for analyses
- BP limits, see 4.16.5, Setting BP limits
- Basis for calculation, see 4.16.8, Extras
- for the control interface
- Language, see 4.16.2, Changing language
- Colours, see 4.16.7, Setting colours for curves and background in graphs
- which window appears after starting the program, see 4.16.8, Extras
- Technical setting
- Interfaces, see 4.16.4, Interfaces
- Database, see 4.16.1, Database
- e-Health Service, see 4.16.3, e-Health service
- Bluetooth, see 4.16.8, Extras.
- GDT settings, see 4.16.9

To set standard values,

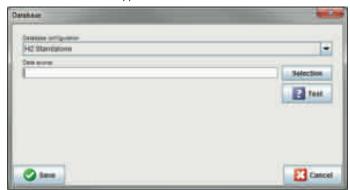
▶ in the menu bar, click **settings** and then the required function.

4.16.1 Database

The patient data and the respective measurements are stored in a database. Here you can set details for accessing the database. For further information, please contact your specialist dealer or I.E.M. GmbH directly.

In the menu bar, click Settings and then Database.

The window Database appears.



- ► Type in the required details.
- ► Click Save

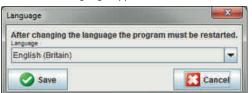
The window disappears.

4.16.2 Changing language

The control interface provides various languages.

▶ In the menu bar, click settings and then Language.

The window Language appears



- ▶ In the pop-up field, click the required language.
- Click Save

The window disappears.

Important!

For the new language to become active, you must quit HMS CS and restart it.

4.16.3 e-health service

Here the access to the e-health server is configured.

▶ In the menu bar, click settings and then e-health service.

The window e-Health service appears.



- ► Type in the required details.
- Click Save

The window disappears.

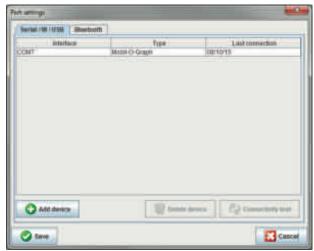
Further information can be found in chapter 4.12

4.16.4 Interfaces

Here you can set the interface that connects the monitor to your PC. Possible connections:

- Cable with serial interface (COM1,2...)
- Combi cable with USB interface
- Infrared (IR) with serial interface
- Infrared (IR) with USB interface
- Bluetooth
- ▶ In the menu bar, click settings and then Interfaces.

The window Interfaces appears.



Setting the type of interface

For a serial, USB or infrared interface

► click the Serial/IR/USB tab.

For a Bluetooth interface

► click the Bluetooth tab.

Setting serial/IR/USB interface for a monitor

► In the Serial/IR/USB tab, click

The window Connection with device appears.



To search for a device,

- switch on the monitor.
- ► Click Search

The device found is displayed in the pop-up list Interface.

If no device is found, a message to this effect appears.

To add the device to the Interfaces list,

► click Save

The window disappears and the new device is shown in the Interface list.

Perform connectivity test for Serial/IR/USB interface

- ► Click the interface of the monitor that you want to test.
- Click Connectivity test

A window appears with the results of the connectivity test.



If no connection to the monitor can be established, a message to this effect appears.

Setting Bluetooth interface for a monitor

The instruction appears: Switch on the Mobil-O-Graph® and change to PAIr mode.

- ▶ Switch on the monitor and change to PAIr mode (see 4.7.2, Connection via Bluetooth).
- ► Click OK

The window Search for Bluetooth device appears.

After a moment, the serial number appears in the window, for example C00607.



- Click the serial number.
- Click Pairing

The message appears: Pairing successful.

- ► Click OK
- Click Save

The new device appears in the window Interfaces in the Bluetooth tab.

Delete a monitor from the list

Click the interface of the monitor you want to delete



<u>Y</u>es Confirm with

The device disappears from the list.

Secure interface

To accept the details you have set,



The window Interfaces disappears.

4.16.5 Setting BP limits

You can specify global thresholds for systolic and diastolic blood pressure. If these values are exceeded, the measurements are marked accordingly in the analyses.

These values are automatically stored as limits for new patients.

The blood pressure limits in children and adolescents aged 0 to 17 years are calculated using the reference tables in the KiGGS study, which give a comprehensive description of the health situation of children and adolescents living in Germany. This has shown that the blood pressure limits of children and adolescents depend on age, sex and size.

The European Society for Hypertension (ESH) published comprehensive tables in 2010 (Management of high blood pressure in children and adolescents: recommendations of the European Society of Hypertension, Lurbe et al.; Journal of hypertension accepted Jun 9 2009), which constitute the basis of the thresholds set for the HMS-CS. The thresholds are determined on the basis of 95% percentile curve.

The limit value can then be defined as one which is either equal or lower for 95% of a whole study cohort (statistic report on 15,000 children).

Any values above this limit are defined as hypertension.

Working with the percentile curve:

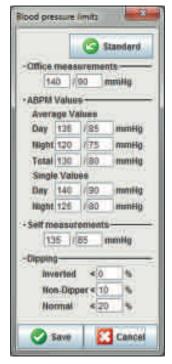
To display the percentile curve (P95) (only for children and adolescents from 3 to 17 years of age) the patient's date of birth must be entered; these data will then be the basis for the calculation of the patient's age performed by the HMS-CS software. IMPORTANT: The analysis will ALWAYS refer to the CURRENT age of the patient. To display a patient history, one print per appointment needs to be made.

Note: You can set BP limits for each patient individually on the Patient information tab (see 4.6, Editing patient information).

Setting limits for analyses

▶ In the menu bar, click settings and then BP limits.

The window BP limits appears.



- ► Type in the required limits.
- ► To accept the new limits, click Save

 The window disappears.

4.16.6 Analysis

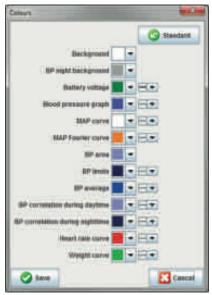
Here you can select different settings for the analysis.

- Initial: Additional start interval to the four day-time intervals
- Static start: Start time of the graphic display
- Tabular display: Here the analysis report can be switched to a tabular display.
- With or without day/night button: Settings for the start times of the four day-time intervals.

4.16.7 Setting colours for curves and background in graphs

▶ In the menu bar, click **Settings** and then **Colours**.

The window Colours appears.



▶ To change colour, in the appropriate pop-up field, click the required colour.



The window disappears.

4.16.8 Extras

Here you can set standard procedures for:

- Calculation of mean (of all single measurements or the hourly mean values (HM)
- Calculation of mean arterial pressure (measured MAP or calculated MAP)
- which measurement analysis will be displayed after transmission of measurements from the device to HMS CS CS (Table of measurements or graph).
- Whether the Patient list will be shown on starting the program, or an "empty" control window appears.
- Whether you are using Bluetooth.
- ▶ In the menu bar, click **settings** and then **Extras**.

The window Extras appears.



- ► Establish your required settings.
- Click Save

The window disappears.

4.16.9 GDT settings

GDT is a data exchange format used by General Practitioners in the German healthcare system. The GDT interface is used to transmit data independently of the type of system between medical measurement devices and practice IT systems.

GDT settings are required for the automatic transfer of patient data between your practice's computers and the HMS CS. If the settings are correct, the HMS CS can be started from your practice's software, and patient data imported directly.

In the menu bar, click Settings and then GDT settings.

The window GDT settings appears.



► Click Selection. Here you can set the directory shared between the HMS CS and your practice's computer system. The HMS CS and practice IT system must have the same setting for the directory. By preference, the program directory of the HMS CS should be set.

- ▶ In the field **Practice IT system -> HMS Client-Server** enter the name of the GDT file that will be exporting patient data from your practice's system to the HMS CS. The same name must be set in both the HMS CS and the practice's system.
- ▶ In the field HMS Client-Server -> Practice IT system enter the name of the GDT file that will be exporting the HMS CS Report to your practice's system. The same name must be set in both the HMS CS and the practice's system.

4.16.10 Manufacturer information

In the menu bar, click on "?" then on "About...".

The Version window will then appear



In the **Version** window, the following information will be shown regarding the Hypertension Management Software:

- Manufacturer information
- · Name and version of the software
- · Versions of the program libraries
- · Version and date of the last build

5. Care and maintenance

To ensure lasting optimal functionality of your Mobil-O-Graph®, regular care and maintenance of the unit is necessary.

Cleaning and disinfection

The user (doctor) decides, whether and when disinfection of the cuff sleeve is necessary for reasons of hygiene (e.g. after each use).

For disinfecting the cuff sleeve, I.E.M. has successfully tested and recommends the following solutions:

- 1. Terralin Liquid (manufacturer: Schuelke & Mayr)
- 2. Isopropanol (70%)

Important: It is vital to observe the manufacturer's instructions for the use of these products. Always leave the solution to dry completely.

Avoid disinfecting the cuff bladder and connected rubber tube. Before disinfecting, take the bladder and the tube carefully out of the cuff sleeve. The bladder and tube may be damaged by disinfectants. Do not place the cuff sleeve in the disinfectant solution. This might damage it.

To achieve the full effect, wet the cuff cover with the disinfectant for at least five minutes.

When using other disinfectants not recommended by I.E.M., the user is responsible for proving harmless application. Never use disinfectants that leave a residue on the product or which are unsuitable for use in contact with skin.

Caution: Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are not sure, remove possible residues with careful washing. The cuff sleeve can be washed in a washing machine at max. 30 °C using a mild washing powder (do not spin). Do not use fabric softeners or other aids (e.g. disinfectant rinses, textile deodorants). These solutions may leave residues and damage the material. The cuff sleeve is not suitable for drying in a tumble dryer. It is important to ensure that the disinfectant is washed off completely before setting the cuff in place. Attention, there must be no residual disinfectant on the blood pressure cuff before setting the cuff in place over 24 hours.

The Velcro must always be fastened before washing.

Bladder: Wash the bladder only with lukewarm water, adding a mild cleaning solution if necessary, and wipe off. Take care to ensure that no water enters the tube opening.

Monitor: Clean the Mobil-O-Graph® only with a damp cotton cloth. Do not use corrosive liquids or solvents. Take care to ensure that no water enters the device.

IMPORTANT: If liquid does penetrate the unit, switch it off immediately and send it to I.E.M. for testing

Pouch: Please clean the pouch only with a damp cotton cloth (do not use corrosive liquids or solvents).

Service plan

Weekly

Check the printout carefully for:

- Correctly entered times and intervals in accordance with the protocol
- Times of day/night changeovers
- Correctness of standard values (nocturnal reduction)
- Battery voltage curve

Checking the battery voltage:

The fully charged batteries are installed in the monitor directly from the charging unit. The battery voltage is shown in the LCD display of the ABP monitor shortly after switching on the device, for approx. 3 sec. This voltage should be at least 2.75V to guarantee measurement over 24 hours.

Every 2 years

As evidence of continuing to comply with the essential requirements of Directive 93/42/EEC, the Mobil-O-Graph® monitor must be subject to metrological checks every two years. In some countries, this requirement may be the subject of national laws or regulations.

We offer to provide you with metrological check and complete servicing.

This service comprises:

- Calibration
- Software update
- Functional testing: electronics, pump and pneumatic circuit.

Batteries

Rechargeable batteries age. Batteries that are damaged, or with which 24-hour monitoring is no longer possible, must be replaced immediately. The batteries will last substantially longer if they drain completely before charging them.

The batteries supplied are of the nickel-metal hydride (NiMH) type. Self-discharge of these batteries depends on the ambient temperature. It is therefore recommended to leave the batteries in the charger until they are actually needed.

We recommend using I.E.M. batteries exclusively, as their capacity and quality has been tested. Care should always be taken that the batteries' capacity is above 1500 mAh.

Battery charger

Follow the operating instructions included with the charger.

6. Troubleshooting

6.1 Principal sources of error

The following may cause faulty measurements or undesired results:

- Arm movement by the patient during the measurement
- Switching off the device (e.g. at night)
- Incorrect cuff size fitted
- Slipping of the cuff in use
- Absence of successful manual measurement in practice
- Failure to take medication
- Incorrect protocol set by the user
- Batteries not fully or correctly charged, or worn out
- Defect in the charging unit

6.2 Battery voltage curve

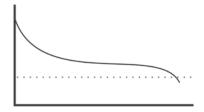


Figure 6.2.1 Rechargeable batteries OK / Batteries OK.

Figure 6.2.2 Batteries old or too little voltage, wrong batteries

6.3 Transmission errors

To avoid errors in data transfer, the monitor checks the data transmitted. If an error has occurred, E004 appears on the display.

6.4 Check list

Please run through the following check list if errors occur when using the Mobil-O-Graph®. Many faults are eas-

- Check whether all cables are securely connected, and the infrared interface is correctly pointed towards the monitor.
- Check whether the monitor, computer and printer are switched on (depending on version obtained).
- Check whether the connector cable is fitted to the correct serial interface (COM1 to COM4).
- Check whether the batteries are adequately charged.

Note: Some errors are associated with a continuous alarm for safety reasons. The continuous alarm can be stopped by pressing any key. If there is pressure remaining in the cuff, open the cuff immediately.

6.5 Error tables

Troubleshooting, Mobil-O-Graph® 6.5.1

Error symptom	Possible cause	Remedy
The time and date are not set to an updated status after a longer period of time without power supply through accumulators or batteries	The internal buffer battery is empty. The biennial calibration has not been performed. The buffer battery is changed at the metrological check.	The date and time can be set after each change of batteries. Send the device for calibration to your dealer or directly to IEM GmbH.
The measurement data can no longer be called up or displayed.	An error has occurred during saving of patient data.	Delete the patient concerned (menu bar) and re-enter.

Error symptom	Possible cause	Remedy
The connection from the Mobil-O-Graph® to the PC is faulty.	The incorrect COM interface is set.	Set the correct interface in the utilities program.
	The cable plug or port is defective.	2. Examine the plug and socket on the Mobil-O-Graph [®] . Make sure that the pins are straight, so that contact is assured.
	The Mobil-O-Graph [®] is not in transfer mode (the time is shown on the display).	Switch the Mobil-O-Graph® off and then on again, without removing the connector cable.
The patient ID number is missing.	The monitor is not initialised, i.e. the patient ID number has not been transmitted during preparation for a 24-hour monitoring session.	The patient ID number can still be transferred after the measurement. The data obtained will not be affected.
No measurements were carried out during the night phase.	The batteries were drained prematurely.	The rechargeable batteries may be defective (please contact your dealer).
	The patient switched off the Mobil-O-Graph®.	Alert the patient to the urgen- cy of obtaining a complete 24- hour recording.
The message co (or bt) does not appear on the display.	You are not in transfer mode.	Communication via cable: Switch the Mobil-O-Graph® off and then on again, without pulling out the plug.
		Communication via IR: Press and hold Start again, and press Day/Night. Use Start to select co.
		Communication via BT: Press and hold Start again, and press Day/Night. Use Start to select bt.
No automatic measurements are performed.	No manual measurement was performed after putting on the equipment.	After putting on the equipment a successful measurement must always be performed manually (see 3.4.6, Putting on the monitor and starting measurement).
	2. Incorrect protocol set.	 Set Protocol 1 or 2 (see 3.4.5, Specifying the measurement protocol required and 4.8.1, Setting the measurement pro- tocol).
The measurement interval is not as you expected.	Incorrect protocol set.	The programmed protocol is not the protocol set in the Mobil-O-Graph [®] . Check the protocol manually (see 3.4.5, Specifying the measurement protocol required).
	No manual measurement was performed after putting on the equipment.	Perform a manual measure- ment to activate the set proto- col.
Err 1	The patient has severe arrhythmia	Monitor not applicable
	The arm was moved during the measurement	Keep the arm still during measurement.
	Not enough valid heartbeats detected	3. Re-fit the cuff
Err 2	The arm was moved during the measurement	Keep the arm still during measurement.
	Cuff not fitted correctly on the arm	Check the fit of the cuff and the monitor

Error symptom	Possible cause	Remedy
Err 3	Blood pressure outside measurement range	If this message continues, the monitor is not suitable for the patient.
	Severe arm movement	Keep your arm still during measurement
	3. Problems with pneumatics	If this error continues, send the unit to your dealer or directly to IEM GmbH for checking.
Err 4	Data transfer cable not correct- ly inserted into the recorder	Plug the cable into the monitor correctly (see 3.4, Preparing for monitoring)
	Pins in plug of data transfer cable have suffered mechanical damage.	Check the plug to see whether pins inside are damaged. If so, call your dealer or IEM.
	Measurement value not cor- rectly transferred.	3. Start the transfer again.
Err 5	Battery voltage too low	Replace the batteries
BAtt	2. Batteries defective	The battery voltage is correct, but during cuff inflation, bAtt is shown on display. Replace the batteries.
	Battery contacts are corroded	Clean the battery contacts with a cotton cloth and some alco- hol
Err 6 + possible continuous alarm until a key is pressed	Air tube blocked	Check the cuff for a blockage or kink in the tube. If there is a kink in the cuff tube, release the tube. Otherwise send the equipment for repair without delay.
	Blood pressure cuff is not cor- rectly connected	2. Connect the cuff with the monitor (see 3.3.5, <i>Cuff connection</i>)
	3. Leak in cuff or connecting tube	If necessary, replace the cuff or connecting tube.
Err 7	The recorder memory is full (maximum 300 measurements and events may be stored)	Delete data from the monitor, but make sure that the data has been saved (see 3.4.2, Clearing the memory)
Err 8	Measurement interrupted by pressing a key	
Err 9 + possible continuous alarm until a key is	Pressure remains in the cuff	Wait for the cuff to deflate completely.
pressed	Zero-point adjustment could not be performed successfully.	Send the unit without delay to your dealer or directly to IEM GmbH for checking.
Err 10 + continuous alarm until a key is pressed	Serious fault due to pressure build-up outside the meas- urement process (pump has switched on illegally)	Send the unit without delay to your dealer or directly to IEM GmbH for checking and repair
	These error messages all indicate a serious error in the program code.	
The analysis unit does not react to data transmission, but co is shown in the display.	Data transfer cable is not plugged into PC	Check whether the 9-pole plug of the data transfer cable is sit- ting securely in the interface port
	2. see also Err 4	2. see also Err 4
The Mobil-O-Graph® takes measurements every two minutes.	Protocol 9 has been set in the Mobil-O-Graph [®] .	Set Protocol 1 or 2 (see 3.4.5, Specifying the measurement proto- col required).

Error symptom	Possible cause	Remedy	
The required protocol cannot be set by pressing key combinations.	Measurements from the last patient are still in the memory	Delete data from the recorder, but make sure that the data has been saved (see 3.4.2, Clearing the memory)	
The monitor cannot be switched on	The batteries were installed incorrectly	Insert both batteries again and check for correct polarity	
	2. The battery voltage is too low	Replace the batteries	
	3. Display defective	Send the unit for repair to your specialist dealer or directly to IEM GmbH.	
A fault occurs during the first measurement.	The cuff does not fit the upper arm of the patient	Using the tape measure supplied, measure the arm circumference and compare it with the printing on the cuff.	

$\hbox{ 6.5.2 } \quad \hbox{Communication errors, Stabil-O-Graph} \\ ^{ \hbox{\scriptsize \'e} }$

Error symptom	Remedy	
Data transfer not possible	The Stabil-O-Graph [®] must display co	
	2. Connect the infrared interface securely with the PC	
	3. Set the correct serial interface (see 4.12.4, Interfaces)	
	4. Correct the direction (see 4.10, Using the Stabil-O-Graph®)	
	5. There are no measurements stored in the Stabil-O-Graph [®] . The measurements are saved only after 10 seconds. Before this is complete, do not touch any Stabil-O-Graph key.	
	6. The computer's serial interface is defective.	
Measurement starts instead of displaying co	Press and hold START/STOP until all segments have been displayed, then additionally press MENU until co appears.	

6.5.3 Communication errors, Mobil-O-Graph® Bluetooth interface

Error	Possible cause	Remedy	
Code 1	Mobil-O-Graph [®] Bluetooth interface has not started up correctly.	Send the unit to your dealer or directly to I.E.M. GmbH for	
	Possible hardware error.	checking.	
Code 2	The Mobil-O-Graph® Bluetooth interface could not be configured correctly.	Try again. If the error continues, send the unit to your dealer or directly to I.E.M.	
	(Communication problem between Mobil-O-Graph® and Bluetooth module.)	GmbH for checking.	
Code 3	The status of the Mobil-O-Graph®	Try again.	
	Bluetooth interface could not be ascertained.	If the error continues, send the unit to your dealer or directly to I.E.M.	
	(Communication problem between Mobil-O-Graph® and Bluetooth module.)	GmbH for checking.	
Code 4	The Mobil-O-Graph® Bluetooth interface is not yet paired with the Bluetooth dongle	Follow the steps in Chapter 4.7.2 Connection via Bluetooth®	
Code 5	The Mobil-O-Graph® Bluetooth	Try again.	
	interface could not connect to the computer's Bluetooth dongle.	If the error continues, send the unit to your dealer or directly to I.E.M. GmbH for checking.	
Code 6	No unsent blood pressure readings exist in the Mobil-O-Graph [®] memory.	As further measurements are taken, these will be sent.	
Code 7	The Mobil-O-Graph® is paired to a mobile phone that is technically incapable of sending the measured values, or has no mobile signal, or is not configured correctly.	Please try again. If the error persists, please contact your retailer or I.E.M	

7. Charging units

A common reason for reduced battery life is incorrect charging. If these batteries are used incorrectly, they lose capacity and are no longer able to supply the Mobil-O-Graph® with power for 24 hours. Should the batteries have lost their charge during storage, please recharge accordingly. For further information, please see the notes in the Operating Instructions for the charging unit.

Tips:

- Charge these batteries fully before using them for the first time.
- Please note that these NiMH rechargeable batteries reach full charging capacity only after their 4th charging cycle.
- Recharge the batteries if they have been unused for some time.
- Do not use batteries that have been stored at above 45 °C or below 0 °C.
- To protect your batteries, avoid deep discharging.
- Should the service life of the batteries sink significantly, replace all the batteries simultaneously. Never use old, used batteries together with new, unused ones!

Care and maintenance:

- Do not immerse the unit in water.
- Clean the unit only when it is separated from the power supply.
- Clean the unit with a soft, dry cloth.
- Do not use cleaning fluids.

Safety instructions:

- Never load non-rechargeable batteries. These may leak or explode and cause damage to health.
- Do not dismantle the unit or the charger cable.
- Cease using the unit if it has been damaged.

7.1 M2X

If you are using the M2X or a structurally identical charging unit, you must observe the following instructions:

- Before using it for the first time, plug the power plug supplied into a mains socket and the small plug into the jack on the charging unit.
- Open the cover of the unit and place 1 to 4 rechargeable batteries individually into the upper level of the charger (check their polarity!). Each shaft has a separate charging circuit, and each of these four circuits can charge a battery.



Figure: M2X model

If the red LED light does not come on, check whether the battery is placed correctly in the shaft, touching the contacts. Should the red light still not come on, the battery can no longer be charged.

If the red light does not change to green after more than two hours of charging (for batteries up to 2000 mAh), the battery is no longer capable of being fully charged and should be replaced.

7. Charging units 7.2

If you leave a battery in the unit, it will be trickle charged so that the battery does not discharge. If you do not use the unit for some time, remove the plug from the power supply.

Because of the unit's high charging current (950 mA for AA and 500 mA for AAA), it should be used only for high-quality rechargeable batteries >1000 mAh (AA) and >500 mAh (AAA). The M2X quick charger has four charging circuits, which enable 1, 2, 3 or 4 batteries to be charged simultaneously. Mignon (AA) micro (AAA), NiCd (nickel cadmium) and NiMH (nickel metal hydride) batteries can be charged. The unit has overload protection.

7.2 TL 4+4 Ultrafast Charger

If you are using the TL 4+4 Ultrafast Charger or a structurally identical charging unit, you must observe the following instructions:

- Before using the unit for the first time, remove the coloured adhesive strip beside the magazine (if available) and connect the power cable with the charging unit and a mains socket.
- Place 1 to 4 rechargeable batteries individually into the upper charger (check their polarity!).
- Note the signals of the upper red LEDs. They indicate the charging process and the completion of charging.
- Remove the charged batteries. (The red light in question must be flashing!)

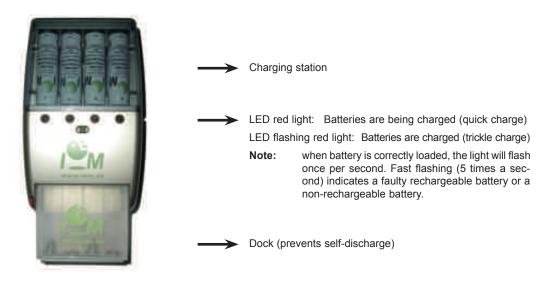


Figure: TL 4+4 Ultrafast Charger model

You can find further information in the operating instructions.

7.3 Operation with alkaline batteries

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

Two alkaline batteries at full capacity have a higher voltage (min. 3.1 V) than 2 NiMH batteries (min. 2.75 V). The battery indicator on the recorder will therefore also show a higher voltage.

Place these batteries in the battery compartment in the same way as the rechargeables (check polarity). After 24 hours remove the batteries and dispose of them.

Remember that batteries are special waste and must be disposed of separately from domestic refuse.



8. Guarantee and repair conditions

Guarantee:

I.E.M. provides a two-year guarantee on the hardware, that is, the actual ABP monitor. The guarantee becomes invalid if the unit has been opened, incorrectly used or damaged deliberately or as a result of negligence. The guarantee also becomes invalid if the equipment has been repaired by an unauthorised person. The user may change only the NiMH batteries.

The guarantee does not cover normal wear and tear of rechargeable batteries, connector cable, cuffs and tube. Under the terms of the guarantee, I.E.M. is liable only for faults that existed when the customer acquired the product (and which may have come to light only later).

Furthermore, this guarantee is not applicable if the fault has been caused by failure to observe the operating instructions, incorrect use, liquids, dampness, extreme temperature and climate conditions or fluctuations, or by corrosion, oxidation, unauthorised interventions or attempts to connect it, unauthorised opening or repair, attempts to repair using unauthorised parts, incorrect operation, incorrect installation, accidents, acts of God, spillage of food or drinks, chemical effects or other external influences (faults in wearing parts such as batteries, which have only a limited lifespan, are also excluded), unless the fault is directly due to flaws in material, construction or manufacture.

Repair:

If the unit has functional errors, or if constant measurement anomalies occur, you should contact your Mobil-O-Graph® specialist dealer or I.E.M. GmbH directly for repair and despatch instructions.

Caution: Do not open the housing. If the unit has been opened, all guarantees become null

MTK:

As evidence of continuing to comply with the basic requirements and general Directives (e.g. 93/42/EEC, Medical Device Operators Ordinance Art. 11 and Appendix 2) the Mobil-O-Graph® monitor must be subject to metrological checks every two years. In some countries, this requirement may be the subject of national laws or regulations

Liability clause:

In all cases in which I.E.M. is obliged by contractual or legal reasons to damages or reimbursement of expenses, we shall only be liable insofar as we, our executive personnel or auxiliary staff can be charged with intent or gross negligence. Liability regardless of fault shall remain unaffected in accordance with the Product Liability Act. Liability for culpable violation of fundamental contractual obligations shall also be unaffected; however, apart from cases in the first and second sentence, liability shall be limited to the predictable damages typical for such kind of contract.

A change in the burden of proof to the disadvantage of the buyer is not associated with the aforementioned regulations. Liability for guarantees of condition or durability or by maliciously concealing a defect is not affected by the aforementioned provisions.

9. Appendix

9.1 EMC guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration - electromagnetic emissions			
The Mobil-O-Graph [®] blood pressure monitor is intended for use in the environment specified below. The purchaser or user of the Mobil-O-Graph [®] blood pressure monitor should ensure that it is used in such an environment.			
Electromagnetic emissions Compliance Electromagnetic environment guidelines			
RF emissions CISPR 11	Group 1	The Mobil-O-Graph® blood pressure monitor uses RF energy purely for its own internal function. RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The Mobil-O-Graph® blood pressure monitor is suitable for use in establishments other than domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.	

Guidelines and manu	Guidelines and manufacturer's declaration - electromagnetic immunity			
The Mobil-O-Graph® blood pressure monitor is intended for use in the environment specified below. The purchaser or user of the Mobil-O-Graph® blood pressure monitor 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) IEC 61000-4-2	± 6kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	
Power frequency (50/60Hz) magnet- ic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

9. Appendix 9.1

Guidelines and manufacturer's declaration - electromagnetic immunity

The Mobil-O-Graph® blood pressure monitor is intended for use in the environment specified below. The purchaser or user of the Mobil-O-Graph® blood pressure monitor should ensure that it is used in such an environ-

Immunity test	IEC 60601- 1-test level	Compliance level	Electromagnetic environment - guidelines
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Mobil-O-Graph® blood pressure monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
			$d = 1.17 \sqrt{p}$ 80 MHz to 800 MHz
			$d = 2.33 \sqrt{p}$ 800 MHz to 2.5 GHz
			where <i>p</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m)
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
			Interference may occur in the vicinity of equipment marked with the "non-ionising radiation" symbol.

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

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

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

Recommended separation distances between portable and mobile RF communications equipment and the Mobil-O-Graph® blood pressure monitor

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

Separation distance according to frequency of transmitter in m							
Rate maximum output of transmitter P in W 80 MHz to 800 MHz d=1.17 \sqrt{p}		800 MHz to 2.5 GHz d=2.33 \sqrt{p}	150 KHz to 80 MHz				
0.01 0.1 1 10 100	0.12 0.37 1.17 3.70 11.70	0.23 0.74 2.33 7.37 23.30	not applicable not applicable not applicable not applicable not applicable				

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

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

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

9.2 Form to copy

9.2 Important instructions for the patient

■ The beep signals a measurement. Keep still during the measurement until the process is complete. Let your arm hang loosely or, when sitting, let your lower arm rest on the table or on a support. Avoid moving your hand during the measurement.

- triggers an additional measurement. Press this key only if instructed to do so by your ■ The Start key doctor (e.g. after taking medication, if you have chest pains or shortness of breath etc.).
- The Event key records the time of an event and triggers a measurement. Press this key only if something important or unusual is happening.
- The Day/Night key should be pressed immediately before going to sleep and upon waking.
- permits the device to be switched on and off if a measurement is not required at the set time. To switch off, press the key for longer than 2 seconds.
- A measurement can be interrupted at any time by pressing any of the keys. This deflates the cuff.

Warnings:

- The cuff may only be worn on the upper arm and in every case you should ensure that neither the shoulder strap nor the air tube can ever become wrapped around your neck. The air tube should therefore always be worn under the outer clothing (even at night).
- Take care to ensure that the tube of the cuff cannot be kinked or compressed, particularly while sleeping.
- If the measurement causes you pain, switch off the device, take off the cuff and inform your doctor.
- The blood pressure monitor must not come into contact with liquids. Do not wear the equipment in the shower! If, for example, water has entered the device, it may no longer be used. Switch off the device and take out the batteries.
- Serious malfunctions are indicated by a continuous beep. If a continuous beep sounds, switch off the device, take off the cuff and inform your doctor.
- The cuff connection (air connector) must always engage with an audible click. Otherwise there will be a leaky connection between the Mobil-O-Graph[®] and the tube that will produce incorrect measurements.

9.3 Accessories order form Mobil-O-Graph®



ABP monitor Mobil-O-Graph® - The 24h blood pressure monitor

Practice:	Dealer's stamp:	
Street:		
Postcode/town:		
Tel.:		
Fax:		
Please give full address!	<u> </u>	
Disease provide a guestation for the following	on itomo	
Please provide a quotation for the followinI wish to order the following items	ig items	
_ 1 with to order the fellowing follow		
Item		Number
Cuff S (20-24 cm)		
Cuff M (24-32 cm)		
Cuff L (32-42 cm)		
Cuff XL (38-55 cm)		
Mobil-O-Graph® Universal Case		
Complete cuff tube, 50 cm		
Air connector for cuff tube		
Battery charger		
I.E.M. rechargeable battery AA 1.2 V		
Batteries AA 1.5 V Pack of 4		
PC combi cable serial		
PC combi cable USB		
Combi Handbook		
Infrared component IR-med serial		
Infrared component IR-med USB		
Bluetooth USB dongle		
HM software for Windows CD update		
PWA-Dongle		
I am interested in a further ABP monitor M	/lobil-O-Graph® NG	
I am interested in another ABD-Monitor Mo	lobil-O-Graph® PWA	
☐ in part-exchange for an old unit	·	
without part-exchange for an old	unit	
without part-exchange for all old	unit	
Date:	Signature:	
		_