

TECHNICAL MANUAL



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1 Introduction

About I.E.M.

I.E.M. is a German manufacturer of compact, high-technological medical equipment in the non-invasive bio-sensory field. The company was established in October 1993 with the aim of achieving innovative, cost-efficient solutions for the public and private health sector. I.E.M. has a selection of highly qualified engineers devoted to research and development, providing a high level of technical support and training to our partners worldwide. The Quality Management System of I.E.M. is certified to EN ISO 9001, EN ISO 13485:2003 and meets 21 CFR 820 (US-QSR).

Target audience

Users of this technical manual are expected to be familiar with the standard medical and electronic terms and practices. The manual is designed to enable authorised hospitals, service technicians and government authorities to repair and calibrate the **Mobil-O-Graph®**.

About this technical manual

This technical manual provides technical information on the Ambulatory Blood Pressure Monitor (ABPM) **Mobil-O-Graph®**. Should any problem occur with your **Mobil-O-Graph®**, please observe the following steps:

- 1.) Read through this technical manual carefully.
- 2.) Document the problem and fax or email the information to I.E.M. or to your distributor with the following details:
 - Name, address, phone number, fax number and contact person
 - Date of purchase
 - Recorder serial number
 - PC software version
 - Detailed problem description
- 3.) If the problem cannot be solved by an initial troubleshooting, please send the device to your distributor or to I.E.M. for repairs. The turnaround time will be 3 working days (depending on severity of repair, exclusive shipping). Please ensure to include a copy of the invoice and your current address to the package.

2 Product description

2.1 Overview

The **Mobil-O-Graph**[®] is an Ambulatory Blood Pressure Monitor (ABPM), using the oscillometric method to measure and calculate the blood pressure and heart rate of a patient over a period which may last 24 hours. The measurements are recorded in the recorder and can be downloaded to a PC with special software or to a special adapted printer with Bluetooth connectivity.

The **Mobil-O-Graph**[®] has the following features:

- 6 digit LCD
- Battery compartment for 2 AA size batteries
- RS232 interface
- IR interface
- Bluetooth connectivity
- Snap connector for cuff
- Four function buttons:

1. **ON/OFF**



2. **START**



3. **DAY/NIGHT**



4. **EVENT**



2.2 Oscillometric method

The oscillometric technique monitors the differences in cuff pressure caused by blood flowing through the brachial artery. No Korotkoff sounds are monitored. The oscillometric method has several advantages:

- No microphone used
- Easy to fit the cuff
- Fast BP measurement
- No noise artifacts

The disadvantage of the oscillometric method is the sensitivity to movement.

2.3 Measurement Cycle

The oscillometric measuring method can be divided into three steps (see Fig. 1):

1. Cuff inflation The cuff is pumped up to a certain predefined pressure that is high enough to cut off the arterial blood flow in the arm.
2. Cuff deflation The cuff pressure is reduced in steps at a controlled rate (actual BP measurement). As the pressure is reduced, the blood begins to flow through the artery. The amplitude of the oscillations in the cuff begins to increase, until a maximum amplitude is reached, after which the amplitude decreases as cuff pressure is reduced. The highest pulse amplitude is referred to as MAP (Mean Arterial Pressure). The systolic and diastolic values are indirectly determined by a complex software algorithm.
3. Rapid cuff deflation The remaining pressure in the cuff is reduced to zero rapidly.

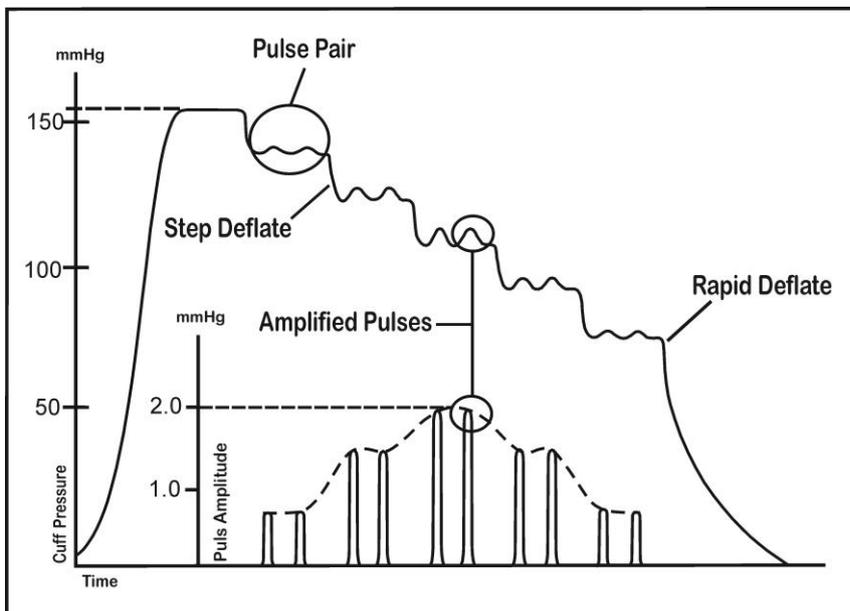


Fig. 1: Cuff pressure and pulse amplitude vs. time

Features of the Mobil-O-Graph®

- Auto feedback logic (AFL)** Based on the last BP measurement, the maximum inflation pressure of the next BP measurement targets a few mmHg above the last systolic BP. This minimizes the patient's discomfort.
- Rapid Stepwise Deflation** The **Mobil-O-Graph®** has built in rapid stepwise deflation to minimize the patient's discomfort.

2.4 The Recorder

The **Mobil-O-Graph**[®] is carried in a pouch that can be hung or strapped to the patient's side. Blood pressure and heart rate measurements are taken using a blood pressure cuff attached to the patient's left arm. The acquired data is recorded to the device and can be downloaded to a personal computer afterwards.

2.5 Front Panel

The front panel is inclined to the rear and consists of four function buttons, a 6 digit LC display and the cuff tube connector (see Fig. 2).

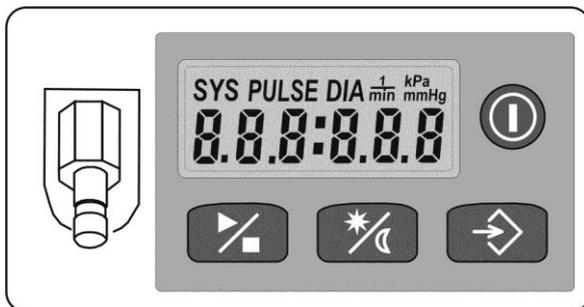


Fig. 2: Front view

2.5.1 Button Functions

The **Mobil-O-Graph**[®] has 4 buttons on its front panel that can be used to activate single actions:

- | | |
|--------------|---|
| 1. ON/OFF |  |
| 2. START |  |
| 3. DAY/NIGHT |  |
| 4. EVENT |  |

2.5.1.1 Actions activated by a single button

ON/OFF

The **ON/OFF** button turns the recorder on and off again. No recorded data is lost when the device is turned off. When the recorder is turned on, the display will do a segment test and show the figures 111:111 up to 999:999. Afterwards, the current battery voltage is shown, followed by the current time. If the RS232 interface cable is connected before turning the recorder on, "co" (= communication) will be shown on the display. The **ON/OFF** button has to be pressed longer than 1 second to turn the recorder off.

START

The **START** button is pressed to start a measurement cycle. The button also allows the patient to initiate an additional, manual measurement at any time, e.g. when the patient feels ill, stressed or excited. When the **START** button is pressed, the number of previously recorded measurements will be shown on the display. Directly afterward the recorder begins to inflate the cuff.

The additional, manual measurement after pressing the **START** button will take longer than a programmed, automatic measurement. The manual measurement will pump up and deflate the cuff in steps as it searches for pulse waves. The automatic measurement will pump up in one smooth curve. If irregular pulse shapes occur due to artifacts or arrhythmia, the recorder will inflate the cuff again within the same measurement.

DAY/NIGHT

The **DAY/NIGHT** button allows a more accurate and individual evaluation by clearly defining the awake and asleep phases. Both the norm values and the frequency of measurements are adapted to the day and night rhythm.

The **DAY/NIGHT** button can be pressed within a time interval of four hours (**-d- -d-** is shown on the display). For example, if the night interval is programmed to begin at midnight (00:00), the patient can activate the night rhythm manually by pressing the button between 8:00 PM and midnight. The recorder will beep when the button is pressed and a measurement will be taken. The manual setting can only be activated once within the four hour time interval. If the measurement is invalid, the **DAY/NIGHT** button can be pressed again directly afterwards to reactivate the day/night function followed by a new measurement. The same principle applies for the morning time interval.

If the patient forgets to press the **DAY/NIGHT** button, the recorder will follow the predefined measurement cycle.

EVENT

The **EVENT** button serves to set markers during a measurement cycle (**-E- -E-** is shown on the display). By pressing the **EVENT** button, a timestamp is added to the current measurement. In the version for printers, an event is visualised on the printout with the comment 'event'. With the software version, an event is visualised on the computer screen in the form of a marker on the time axis of the evaluation.

The patient is instructed to press the **EVENT** button whenever taking a medication. Furthermore the **EVENT** button should be pressed when extraordinary symptoms occur, e.g. when the patient feels abruptly ill, stressed or excited, followed by the **START** button to record an additional manual measurement.

The patient should be advised to document the reasons for pressing the **EVENT** button in a diary.

2.5.1.2 Actions activated by button combinations

START (longer than 5 seconds)

The memory can be deleted manually by pressing and holding the **START** button for at least 5 seconds. While holding the **START** button, all segments of the LCD are highlighted followed by a single beep. Afterwards, the number of recorded measurements is shown, followed by "**clr**". Within the next 5 seconds press and hold down the **EVENT** button for at least 2 seconds to delete all recorded measurements from the device.

START + EVENT

Pressing the **START** and **EVENT** button simultaneously sets the recorder to the **time/date** mode. The first minute digit on the LCD will flash. By pressing the **START** button the flashing digit is increased in steps. By pressing the **EVENT** button the next digit is activated.

After the time, the date (MM DD) and the year can be set. When no button is pressed for 20 seconds, the **time/date** mode will be exited automatically.

Change the time and date only if the memory of the recorder is empty.

START + DAY/NIGHT

Pressing the **START** and **DAY/NIGHT** button simultaneously sets the recorder to the **interface selection** mode.

The letters "**bt**" (= bluetooth) start flashing on the display. Pressing the **START** button again changes the setting to "**co**" (= communication via cable interface) and then to "**PAIR**".

"**PAIR**" is used for the pairing (first connection) between the recorders Bluetooth interface and the computers Bluetooth interface. After setting up the connection, select "**bt**" to use the Bluetooth interface.

ON/OFF + inserting the batteries

This combination sets the recorder into **manometer** mode.

2.6 Side Panel

The left side of the housing (see Fig. 3) includes a port for the data communication cable (serial RS232 port). The cable is attached by gently positioning the plug on the communication port and lining up the pins. Without twisting the plug slide it in gently. Never use force!

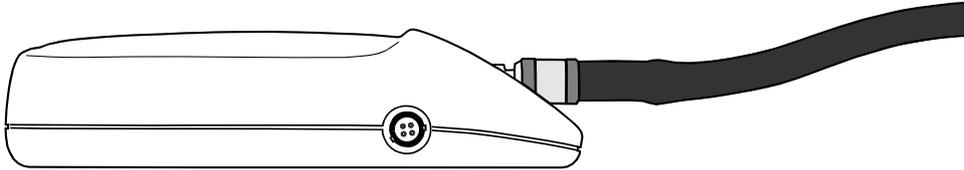


Fig. 3: Left side panel with the serial port

The right side of the housing (see Fig. 4) includes an IR port for the communication via IR interface.

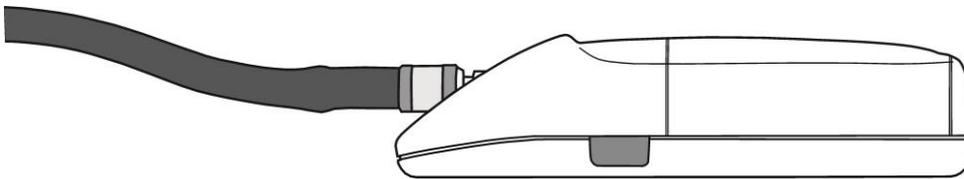


Fig. 4: Right side panel with the IR port

2.7 Top Side

The top of the recorder includes the battery compartment (see Fig. 5). Place a thumb on the battery compartment cover and exert light pressure to slide the compartment cover to the side. When replacing batteries, always check the correct polarity!

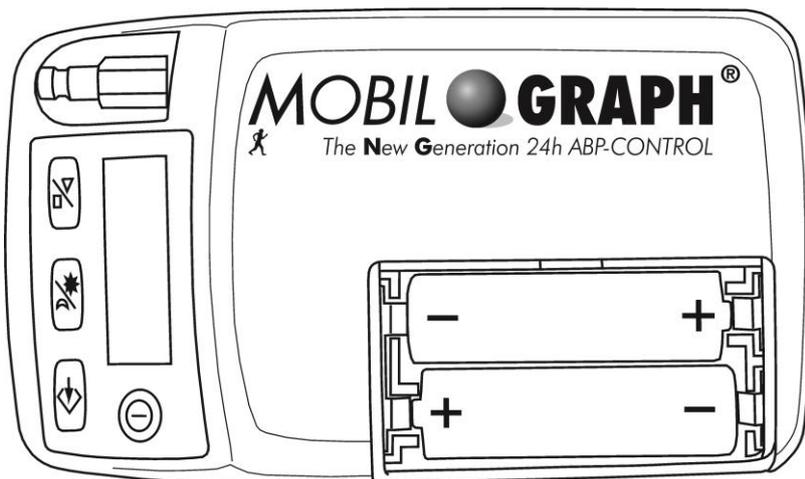


Fig. 5: Battery compartment

2.8 Bottom Side

The lower housing part contains a label to identify the device's serial number, I.E.M's service address and the CE mark (see Fig. 6). The latter is issued after an exhaustive clinical and technical evaluation through the Notified Body TÜV Nord Cert GmbH, Essen, Germany..



Fig. 6: Label on the lower housing

2.9 Accessories

- Mobil-O-Graph®
- 4 ergonomically designed cuffs: Adults (x-small, small, normal, large and x-large)
- Battery charger (certain markets only!)
- 4 rechargeable NiMH batteries (certain markets only!)
- Tube connector
- User manual
- Short guide
- Hypertension Management Software
- Pouch with belt
- Tape measure
- Connection cable RS232, 9-pin interface on the PC side and a 4-pin plug on the recorder side
- Infrared adapter, 9-pin interface or USB on the PC side (optional)
- Bluetooth interface dongle (optional)

3 Application Software

3.1 Recorder Software

The recorder software is loaded from a PC and remains in the CPU of the recorder. Only I.E.M. or key distributors have access to this software. It is **not** intended to be used by physicians or medical personnel.

3.2 User Software

The **Mobil-O-Graph**[®] system consists of two software packages. The Hypertension Management Software (**HMS**) for Windows designed for stand-alone PC users and the Hypertension Management Software Client-Server (**HMS CS**) designed for using the internet e-health system of I.E.M and other operating systems like Linux or Macintosh. Every customer using older software than the HMS for Windows 7.0 version needs to request an update.

3.3 Hardware Requirements

The hardware requirements for running the PC software for the **Mobil-O-Graph**[®] system:

3.3.1 Hypertension Management Software - Windows Version

- Personal Computer, 100% IBM-compatible, 80486 ff., 40 Mhz
- CD-ROM Drive
- min. Windows 95
- VGA
- min. 32 Mbytes RAM
- min. 10 Mbytes free memory on hard disc
- one free serial / USB port
- Printer as any Windows compatible

3.3.2 Hypertension Management Software - Client Server Version

- 1 GHz
- CD-ROM Drive
- Windows 2000 SP4, XP, Vista
Mac OS X 10.4 or newer
Linux with Intel-/AMD-Processor, GNU/Linux with BlueZ/Affix Bluetooth
- 1024x768 Pixel
- min. 512 MB RAM
- min. 100 Mbytes free memory on hard disc
- one free serial or two spare USB ports

3.3.3 PC Data Communication Cable

The PC communication cable consists of 4 single leads: RxD, TxD, GND and NC (not connected). The PC side of the cable consists of a female 9-pin interface that contains several bridges:

- Bridge 1: Pins 1, 7 and 8 are all connected together by a bridge.
- Bridge 2: Pins 6 and 4 are both connected together by a bridge.

The recorder side of the cable consists of a 4-pin jack. The 4-pin jack is shown in Fig. 7. Pins 1 and 4 are bridged. The pin numbers are **not** printed on the casing.

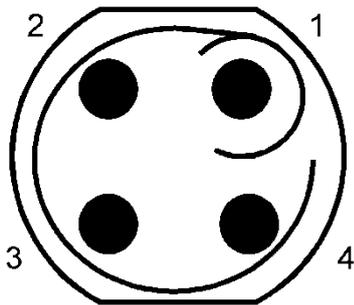


Fig. 7: 4-pin jack, shown from the solder side

Table 1: Connection 4-pin jack to 9-pin interface

4-pin jack	9-pin interface	Signal
-	1	DCD
2	2	RxD
3	3	TxD
-	4	DTR
1	5	GND
-	6	DSR
-	7	RTS
-	8	CTS
-	9	
4	Casing	GND

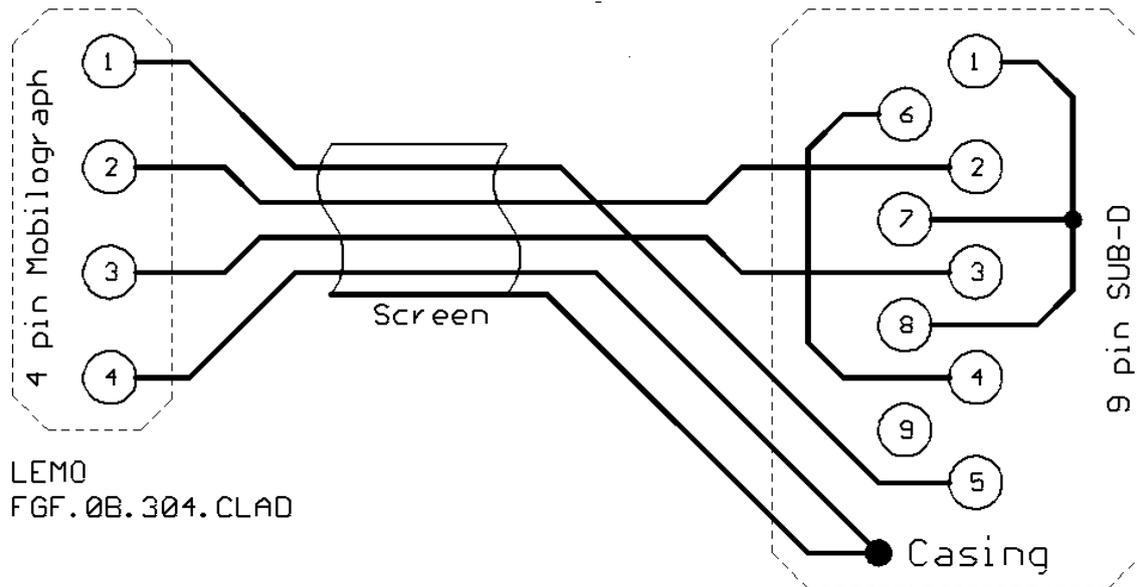


Fig. 8: Connection 4-pin jack to 9-pin interface

3.3.4 Bluetooth Interface (only for HMS Client Server Version)

- Bluetooth USB adapter
- Bluetooth 2.0
- USB Version 1.1 or higher
- **BlueSoleil driver or software must not be installed!**
- Tested USB adapters:
 - Gigabyte GN-BT03D
Windows XP SP2: Automatic installation with Microsoft Stack
 - ANYCOM USB-200 or USB 250 Blue USB adapter
 - Windows XP, Windows XP SP2: installation of supplied driver for Windows XP Bluetooth Stack or installation of supplied Bluetooth software BTW
 - Windows 2000, XP, Mac OS X 10.4 or newer: Installation of supplied Bluetooth Software BTW
 - GNU/Linux 2.4, GNU/Linux 2.6 with BlueZ or Affix Bluetooth Stack: No installation necessary

3.3.5 IR-Interface (only for HMS Client Server version)

Only the IEM IR-Interface IR-MED is usable.

3.4 Hypertension Management Software for Windows

The software is designed for the stationary preparation and evaluation of the **Mobil-O-Graph®** on a PC with Windows 95 / 98 / NT / 2000 / ME / XP.

This software bases on the PC software of the forerunner model **Mobil-O-Graph** and is a 16 bit solution. A complete downward compatibility to the forerunner model **Mobil-O-Graph** is guaranteed. Therefore the doctor needs only single software for all **Mobil-O-Graph®** models.

On the basis of the 16 bits solution, the Bluetooth interface is not usable with this software, because Bluetooth drivers work only with 32 bit. However, the serial port and the IR interface can be used. Such, this software provides a professional and approved tool to use the **Mobil-O-Graph**[®].

Please refer to the instructions for use provided with each device for information on use of the software.

For further information please take a look to the respective instructions for use.

3.5 Hypertension-Management-Software Client-Server

The software is designed for the preparation and evaluation of the **Mobil-O-Graph**[®] with the option to supplement the evaluation with the internet e-health system (tele monitoring) from I.E.M.

This software bases on the 32 bit Java application and is compatible with Windows 95 / 98 / NT / 2000 / ME / XP / VISTA, Linux, Macintosh, Sun and other Java compatible systems.

A complete downward compatibility to the predecessor model **Mobil-O-Graph** is guaranteed. Therefore the doctor needs only single software for all **Mobil-O-Graph**[®] models.

For further information please take a look to the respective instructions for use.

3.6 Troubleshooting Hypertension Management Software for Windows Version 7.0

1) No reply from Interface

Cause:

- a) Wrong interface chosen
- b) Wrong baud rate adjusted
- c) Wrong IR device defined
- d) IR device is not connected to PC
- e) **co**-mode is not activated in the **Mobil-O-Graph**[®] interface menu

Corrective action:

The distance between IR device and **Mobil-O-Graph**[®] should not exceed 1 meter.

- a) The active connection must be changed under "settings" / "Recorder Interface".
- b) The baud rate must be changed to 9600 baud under "settings" / "Interface for Recorder".
- c) The appropriate IR device must be chosen under "settings" / "Recorder Interface" The distance between IR device and **Mobil-O-Graph**[®] should not exceed 1 meter.
- d) The IR device/ **Mobil-O-Graph**[®] cable must be connected to the com port on the backside of the PC. In case of connection problems, please use a 9-15 gender changer.
- e) Press and hold the **START/STOP** button while pressing the **DAY/NIGHT** button.

Remark:

The functionality of the IR interface and the choice of the correct port could be confirmed by testing a function of the recorder (e.g. Buzzer).

2) Invalid or not supported Interface indexCause:

Port for **Mobil-O-Graph**[®] is not selected.

Corrective action:

Choose the right port under “settings” / “Recorder Interface”.

3) In the measurement series appear values of a wrong patientCause:

Stored patient values were not deleted in **Mobil-O-Graph**[®].

Corrective action:

Single values cannot be deleted, but deactivated. For this you have to mark the number of the measurement with the left mouse button; the number appears in brackets. The measurement is now excluded from statistical calculations.

4) Wrong measurement date (e.g. 01.01.2006)Cause:

The back-up battery might be empty. Probably the service interval (2 years) was not maintained.

Corrective action:

After each change of accumulators, date/ time settings must be readjusted before a new measurement series starts. The device should be sent as soon as possible to the service.

5) Checksum error: While data transfer from Mobil-O-Graph[®] to PC an error occurredCause:

If the **Mobil-O-Graph**[®] beeped while reading the measurements, entries were adjusted in the EEPROM.

Corrective action:

It is advisable to send the device with a corresponding commentary to the service.

6) Settings are not stored in the ABDM.INICause:

If the Windows account is only describable for the Administrator, ABDM.INI items seem to be made, but they are not really stored. By next opportunity the “old” settings are active again.

Corrective action:

Allow writing access on the ABDM.INI.

Remark:

In the file “Writelni” an advice should be inserted (e.g. “The settings cannot be changed”). Ensure that “& GetWindowsDir() & Ini_Name &” are not write-protected.

7) **Hardware is not available**

Failure description:

While reading out or preparing the recorder an USB adapter problem occurred:
Hardware is not available!

Cause:

Power failure -> USB Adapter is not dedicated to the correct COM-Port

Corrective action:

Remove USB Adapter and then connect again. Afterwards start the automatic COM-Port search again. Maybe reinstall the driver or restart your computer.

8) **Error in FillMessArray()**

Failure description

While the choice of a Mobil-O-Graph[®] measurement series the following Error occurs: "Error in FillMessArray()"

Cause:

The country settings are english and the time format is H:mm:ss:xx
Probably the time format is the cause

Corrective action:

Country settings: e.g. Germany (Standard)

Time format: HH:mm:ss

Short date format: DD.MM.YYYY (German: TT.MM.JJJJ)

4 **Service Software**

The service software consists of two parts:

- **Mobil-O-Graph[®]** service software (Mob-Inspector)
- Flash Software (to program the processor with new firmware)

The software is designed for the stationary preparation and evaluation of the **Mobil-O-Graph[®]** on a PC with Windows 2000 / ME / XP.

4.1 **Mobil-O-Graph[®] service software (Mob-Inspector)**

4.1.1 **Installation**

System requirements: Microsoft Windows ME, 2000 or XP.

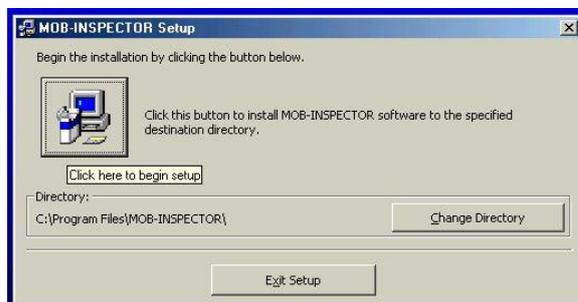
Follow the instructions below:

- Start **setup.exe** from the CD-ROM.

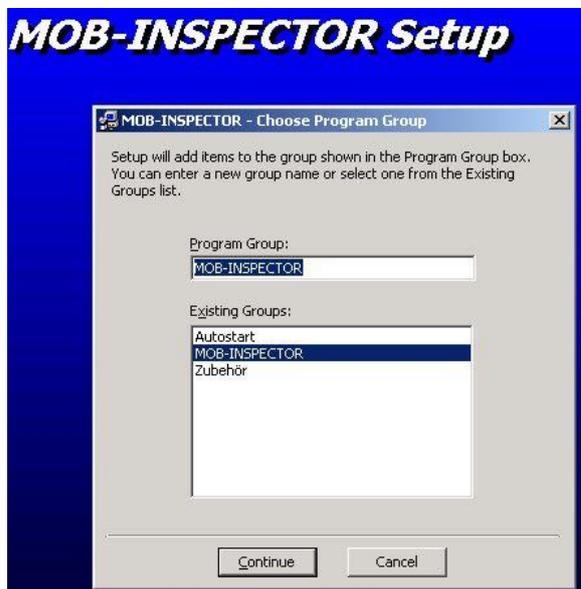
- Click OK.



- Click on the large PC symbol button.



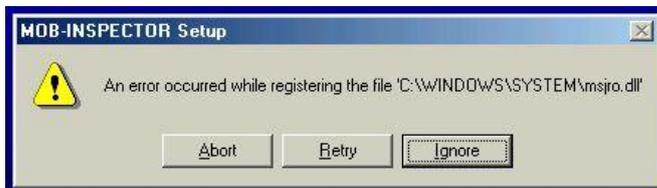
- Click Continue to install the software.



- If a Windows version conflict appears: Please press **“YES”**.



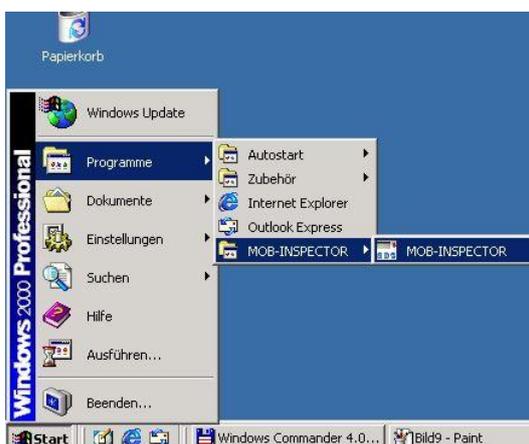
- If you receive an error note while registering any .dll please press **“OK”** and afterwards **“Ignore”**.



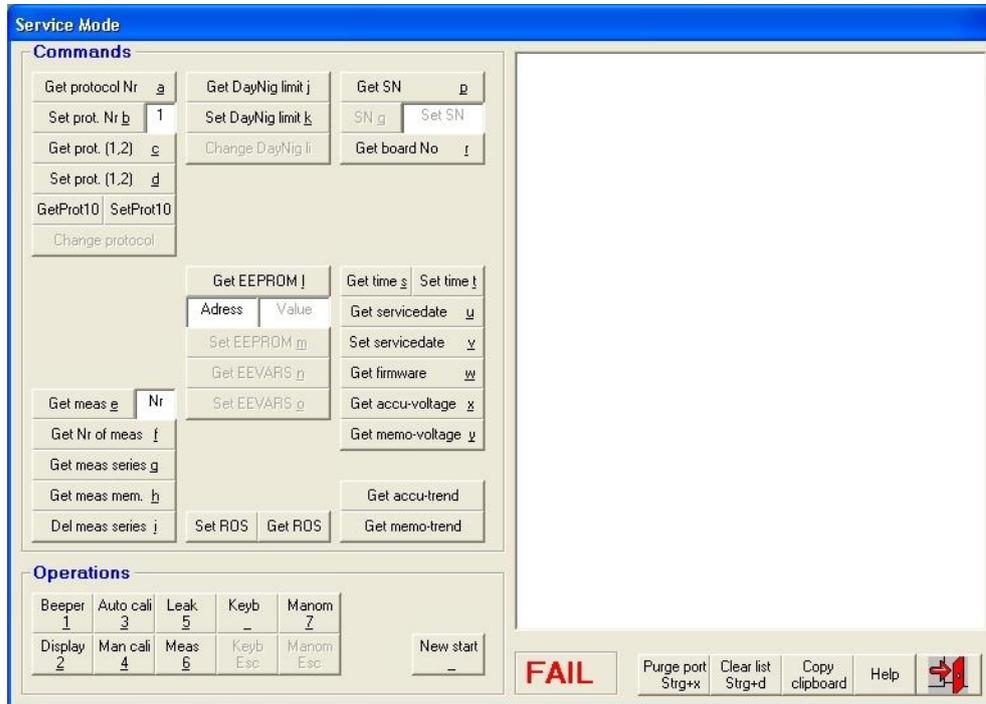
- To finish the installation, please press OK.



- Start the MOB-Inspector software as follows.



- To enter the service area please confirm **date and time** and enter the **password “1234”**.
- The following window appears:



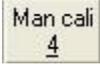
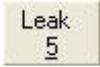
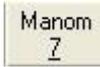
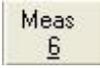
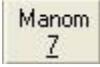
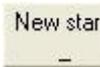
4.1.2 Commands

Get protocol Nr <u>a</u>	The number of the active protocol is shown.
Set prot. Nr <u>b</u> 1	Activates a new measurement protocol (protocol 1-10).
Get prot. (1,2) <u>c</u>	The measurement intervals of protocol 1 & 2 are displayed.
Set prot. (1,2) <u>d</u>	Default measurement intervals for protocol 1 & 2 are set.
GetProt10 SetProt10	Default measurement intervals for protocol 10 are get or set.
Get meas <u>e</u> Nr	A single stored measurement value is shown by entering the corresponding number to the empty field.
Get Nr of meas <u>f</u>	The number of measurements of the last “24h measurement series” is shown.
Get meas series <u>g</u>	All stored values of the last “24h measurement series” are displayed.
Get meas mem. <u>h</u>	The last 300 (internal: 600) stored measurement values and the last 100 detail error codes are displayed.
Del meas series <u>j</u>	Deletes all stored measurement values.

Get DayNig limit j	Shows the current systolic and diastolic limits for day and night settings. (HMS – Software)
Set DayNig limit k	Default settings of systolic/diastolic limits for day/night. (HMS – Software)
Get EEPROM l Adress Value	A single EEPROM value is shown by enter the accordant address to the empty field.
Set ROS m Get ROS n	E-health server calling number is get or set. All measurements that are done with protocol 10 are transferred to this server if a mobile phone or modem is connected with the Mobil-O-Graph® .
Get SN o	Shows the serial number of the Mobil-O-Graph® .
Get board No p	Shows the production no. of the Mobil-O-Graph® mainboard.
Get time q	Shows the current date and time of the Mobil-O-Graph® (DD.MM.YYYY) (HH:MM:SS).
Set time r	The system time of the computer, where the Mobil-O-Graph® is connected with, is adjusted.
Get servicedate s	Shows the date of next metrological control/calibration.
Set servicedate t	Manual input of the next metrological control date (Calibration is recommended).
Get firmware u	The current Firmware version is shown.
Get accu-voltage v	The current battery/accumulator voltage is displayed.
Get memo-voltage w	The current memory battery voltage is displayed.

4.1.3 Operations

Beeper 1	Test of the accurate function of the internal buzzer of the Mobil-O-Graph® .
Keyb -	Test of the accurate function of the keyboard. While pressing buttons one after another the numbers 8, 4, 2 and 1 have to appear on the LCD. To leave the keyboard test you have to click on the button Keyb Esc .
Display 2	Test of the accurate function of all segments on the LCD. The Mobil-O-Graph® must show all viewable digits from zero upwards (optical control is necessary).
Auto cali 3	Automatic calibrations function of the Mobil-O-Graph® . Follow the software description. This function is only available by using the Digital manometer HM28 (Revue Thommen AG) and an appropriate RS232-Interface.

	<p>Necessary equipment:</p> <ul style="list-style-type: none"> - 200 ml Volume - Digital manometer HM28DOH20100 (REVUE THOMMEN) with RS232-Interface - Tube and 2 tube-T-connectors <p>If the Digital manometer HM28 is not available, please use the “Manual calibration function”.</p>
	<p>Manual calibrations function of the Mobil-O-Graph®. Follow the software description.</p> <p>Necessary equipment:</p> <ul style="list-style-type: none"> - Inflator - 200 ml Volume - Digital manometer - Tube and 2 tube-T-connectors
	<p>Automatic leakage check of the Mobil-O-Graph®. Follow the software description.</p> <p>This function is only available by using the Digital manometer HM28 (Revue Thommen AG) and an appropriate RS232-Interface.</p> <p>Necessary equipment:</p> <ul style="list-style-type: none"> - 200 ml Volume - Digital manometer HM28DOH20100 (REVUE THOMMEN) with RS232-Interface - Tube and 2 tube-T-connectors <p>If the Digital manometer HM28 is not available, please use the monometer mode. See chapter 2.4.1 or use the button  !</p>
	<p>One blood pressure measurement is done.</p>
	<p>The manometer modus of the Mobil-O-Graph® is activated, a zero appears on the right side of the LCD. Any pressure at the cuff-connector will be shown.</p> <p>(To leave the manometer modus press ).</p>
	<p>New initialization of the Mobil-O-Graph®.</p>

4.2 Flash Software

On the basis of an improvement or bug fixing, it could be necessary to load a new firmware to the recorder. The internal main processor of the recorder can be loaded from a personal computer with a new firmware by using the Flash Software and a data communication cable. Therefore connect the serial interfaces of the personal computer and the recorder.

4.2.1 Installation

System requirements: Microsoft Windows ME, 2000 or XP.

Follow the instructions below:

- Start **setup.exe** from the CD-ROM
- Click OK.



- Click on the large PC symbol button.



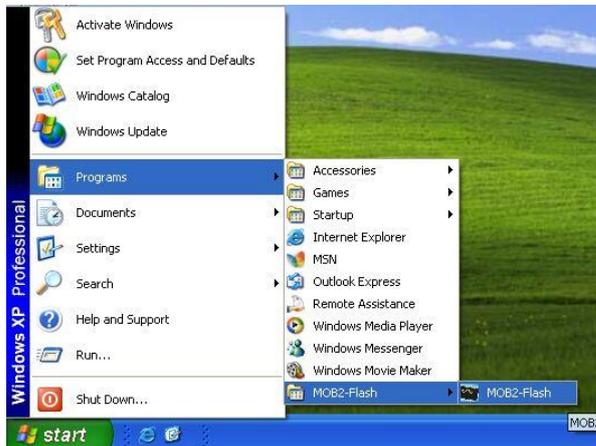
- Click Continue to install the software.



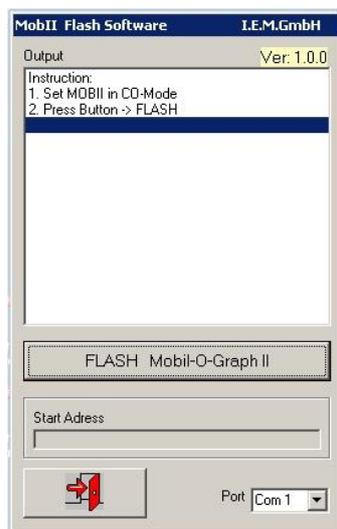
- To finish the installation, please press OK.



- Start the MOB-Inspector software as follows.



- After turning on the recorder, “**co**” should appear on the recorder’s LCD. The recorder is now set into the **Communication Mode**.



- After executing the Flash program and pressing the button “FLASH Mobil-O-Graph” it shows the directory with the last used file. The user can select the right file (e.g.: MOBII_090307_Flash.txt).



- After the file is selected by a double-click, the flash program starts the download process of the new firmware to the recorder. During this process '- - - - -' should appear on the LCD.

Attention: Don't do anything during the flash-process!!!

If the process is disturbed or aborted, the processor of the recorder is destroyed and can only be repaired by IEM.

5 Calibration control

The **Mobil-O-Graph**[®] system is delivered fully checked, tested and calibrated. However, I.E.M. recommends re-calibrating and thoroughly checking the device approximately every 2 years.

The present test instruction describes the performance of the calibration control (MTK "Measurement technical control" → Calibration control or measurement check) as required by several international regulations and guidelines, and by I.E.M.

The described calibration control applies to the **Mobil-O-Graph**[®] and its OEM-versions.

5.1 Responsibilities

I.E.M. takes no responsibility for all adjustments and manipulations of the **Mobil-O-Graph**[®] which are performed outside of I.E.M.

5.2 Procedure

For all professional use, the calibration of blood pressure monitors is required every two years, according to several international regulations and guidelines. General conditions for performance and requirements regarding the performing personnel may be laid out in some national legislation. Refer to the regulations of your country.

5.3 Qualification

In case other parties than I.E.M. will perform a calibration control on our devices, IEM needs to assure the qualification of these parties. The requirements for the calibration control include competent

personnel that can prove education in a corresponding technical scope of work. All external parties performing calibration control for the **Mobil-O-Graph®** need to have this test instruction available.

5.4 Equipment

Following equipment is needed to perform the MTK:

1. Calibrated reference manometer (digital or analog) with maximum measurement deviation of 0.8 mmHg or 0.1 kPa.
2. Stop watch with maximum deviation of 0.1 s.
3. Pressure generator (e.g. manual pump ball) with deflation valve
4. Rigid reservoir with volume of $200\text{cm}^3 \pm 5\%$
5. Tubing with about 3m length, 3mmID, 8mm OD
6. 2 T-connectors for the tubing (can be purchased at IEM)
7. Mobil-O-Graph cuff connector (can be purchased at IEM)
8. Mobil-O-Graph PC-cable 4 Pin (can be purchased at IEM)
9. Mobil-O-Graph Service Software CD
10. Measurement record (form)
11. Literature: **EN 1060, Part 1 and 3; and applicable national regulations, such as e.g. "LMKM" "Guidance on calibration control of medical devices with measuring function", PTB, each in the most current revision.**

5.5 Renew the internal Lithium-cell CR2032

The lifetime of the internal Lithium-cell is 2.5 years. If the battery should run flat, the doctor must set the time of the **Mobil-O-Graph®** before each measurement series. Therefore I.E.M. recommends replacing batteries, which were inserted more than a half year prior to the calibration control.

How to replace:

- Open **the Mobil-O-Graph®** as show in Fig. 9
- If it is not possible to open it with your fingernails, use a tool like a screwdriver, but be careful with the plastic edges.

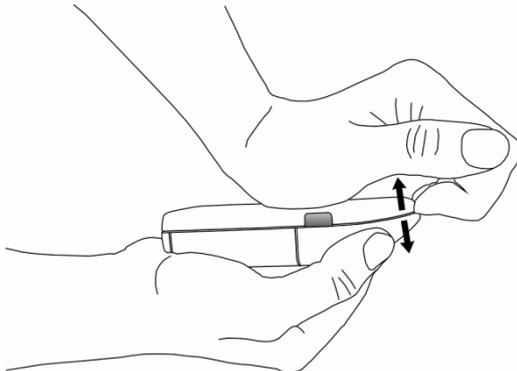


Fig. 9

- Change the Lithium-cell as shown in Fig. 10.
To prevent discharge, do not touch both contacts of the battery (+/-) with your fingers or a tool at the same time!

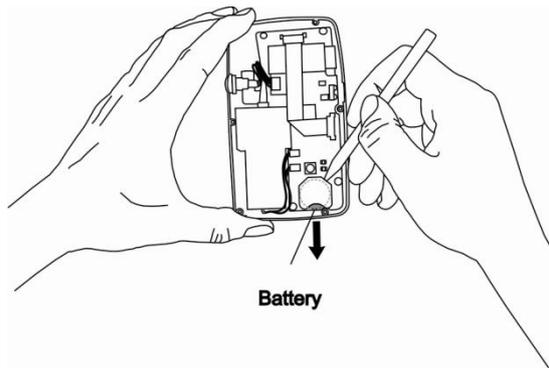


Fig. 10

5.6 Perform the MTK

- Connect the reference manometer to the system.
- Replace the cuff by the 500 cm³ metal reservoir.
- Press and hold the **ON/OFF** button while inserting the batteries to switch the **Mobil-O-Graph**[®] into the manometer mode.
- Press the **START** button or use the hand manometer to inflate the system up to 300 mmHg (at the same time this is a pump function test).
- Reduce pressure stepwise to 250, 200, 150, 100, 50 mmHg. At each step wait for 10 seconds. At each step compare the value displayed by the device with the reading of the manometer. Fill read values into the record, calculate and document deviations.

The maximum allowed deviation for each step is ± 3 mmHg (EN 1060-1).

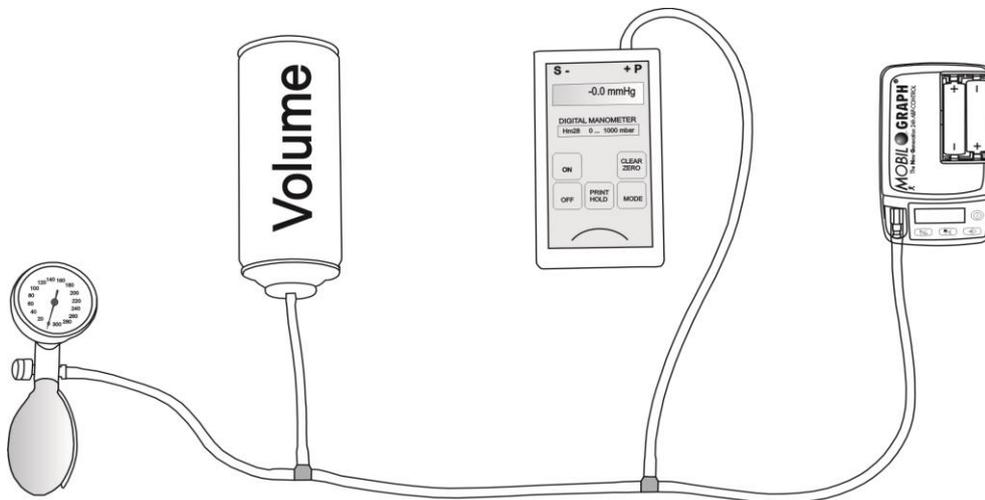


Fig. 11: Schematic of the system

5.7 Wrong pressure values

Any device that fails to meet the acceptance criteria (± 3 mmHg), the static pressure measurement has to be newly adjusted.

To perform the new adjustment, please use the function manual calibration

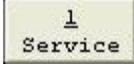
Man cali
4

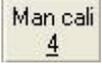
or auto calibration

Auto cali
3

of the service software (Mob-Inspector).

- Connect the digital manometers, manual hand manometers and the **Mobil-O-Graph**[®] (turned off) to one pneumatic system (see Fig. 12).
- Connect the **Mobil-O-Graph**[®] to the personal computer and start the program Mob-Inspector.

- Click the button  to start the service area.
- Enter the password "1234"
- The recorder can now be turned on; 'co' appears on the LCD.

- The system is switched to the calibration mode by selecting the button .
- The actual calibration begins by determining the zero value. To do this, open the valve on the hand manometer so that all residual pressure can escape from the system. This zero value is then confirmed within the software. Press (ENTER).
- The software will now demand a calibration at 200 mmHg. To do this, close the valve on the hand manometer and press the **START** button on the **Mobil-O-Graph**[®]. Pressure is built up and can be regulated to 200 using the hand manometer.
- The system should maintain the pressure at a constant level of 200 mmHg, this should be confirmed in the software by pressing (ENTER).
- The recorder now is calibrated.

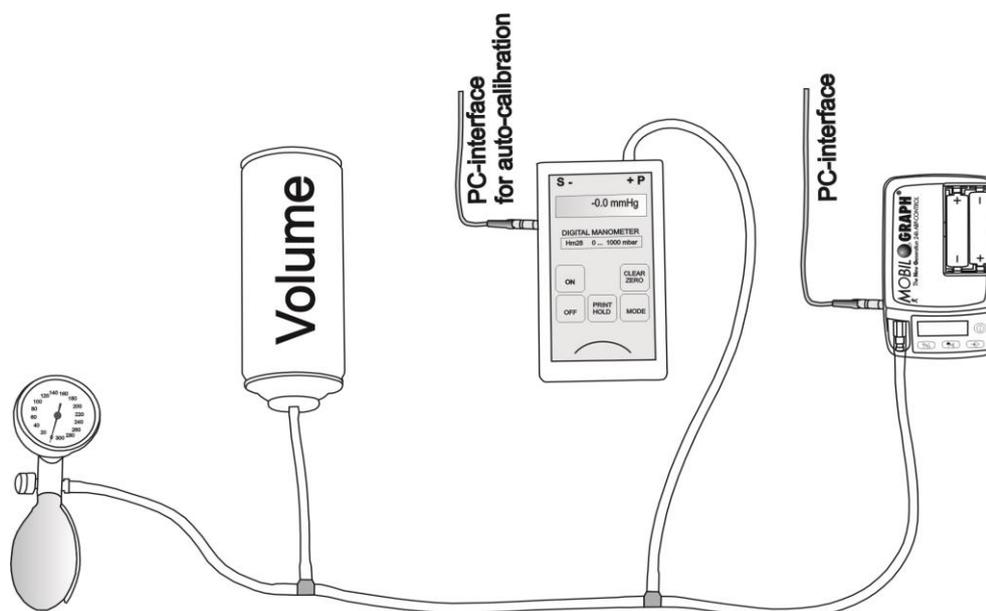


Fig. 12: Schematic presentation of the calibration procedure

5.7.1 Function check

A function check is performed with a volunteer or a patient simulator. It checks that the measurement procedure runs correctly as described in the manual. When used as intended the device must give reasonable results.

5.7.2 Leakage test (complete system, no manometer)

- Switch the **Mobil-O-Graph**[®] into manometer mode (press and hold the **ON/OFF** button and insert the batteries. After 2 seconds the device displays "0").
- Wrap the cuff around a cylinder of appropriate diameter.
- Press the **START** button shortly to pump air in the system.
- Pressurize up to 200mmHg using the manual pump, wait for 20 seconds.
- Watch the pressure loss over 60 seconds (use stop watch); max. 6mmHg leakage is allowed.
- Repeat the same test at pressure level.

5.8 Documentation

The performance of a MTK is documented using a report form. The original record is passed to the customer, the inspector keeps one copy. The device must clearly show an indicator of a performed MTK (sticker). This sticker does at least show next due date for calibration control and the tester who performed the control.

6 Repairing

There are some problems that could be repaired by parties other than I.E.M. Repair is limited to the replacement of some modules (components). Repair may only be performed by competent personnel that can prove appropriate education in a corresponding technical scope of work. All repair personnel is accountable for their own troubleshooting of the **Mobil-O-Graph**[®]. The product is too complex for a whole troubleshooting description in this manual.

6.1 Responsibilities

- The **Mobil-O-Graph**[®] loses any guaranty by I.E.M. if parties other than I.E.M. and/or not authorized by I.E.M. open the device.
- It is strictly forbidden to solder on the PCB's of the **Mobil-O-Graph**[®].
- External parties have to record all replacements of components. Especially the lot numbers of the pump, the valve and all PCB's have to be documented for 10 years!
- I.E.M. takes no responsibility for all repairs or adjustments or other servicing of the **Mobil-O-Graph**[®] which are done outside of I.E.M.

6.2 Modules that can be replaced

Pump:

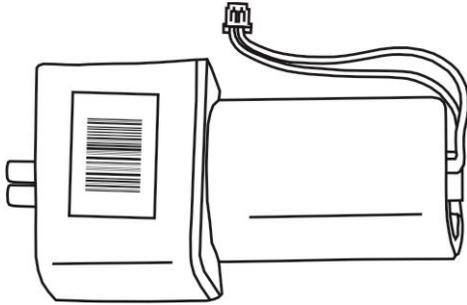


Fig. 13

The Pump is connected to the pneumatic system with the silicon tube and to the mainboard via a wire-to-board connector.

How to replace:

- Open the housing as shown in Fig. 9.
- Disconnect the wire-to-board connector from the mainboard.
- Separate the pump from the silicon tube connector.
- Prepare the pump with a new air filter. Put the filter on the pneumatic connector which has the smaller inside diameter as shown in Fig. 14.

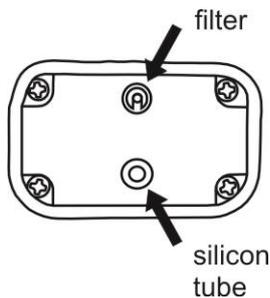


Fig. 14

- Insert the new pump with the pneumatic connector which has the bigger inside diameter downward and press the downward connector completely into the silicon tube.
- Connect the wire-to-board connector to the mainboard.
- Close the housing.

Silicone tube:

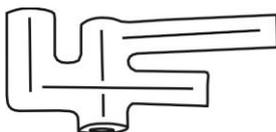


Fig. 15

The silicone tube connects the pressure sensor on the mainboard, the cuff connector, the pump and the valve to a pneumatic system.

How to replace:

- Open the housing as shown in Fig. 9.
- Take the pump out of the device.

- Disconnect the wire-to-board connectors on the mainboard and remove the 2 screws (see Fig. 16).

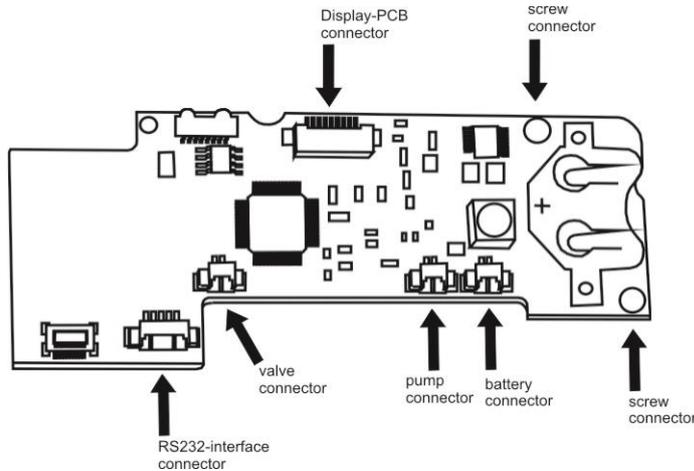


Fig. 16

- Remove the mainboard and disconnect the silicon tube from the pressure sensor.
- Disconnect the silicon tube from the valve and the cuff connector.
- Replace the silicon tube and assemble the **Mobil-O-Graph**[®] in reverse sequence.

Valve:

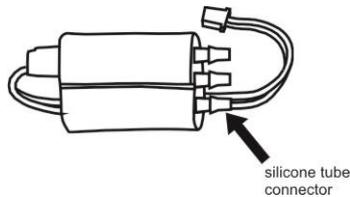


Fig. 17

The valve is a very important component, because it is responsible for the right deaeration of the **Mobil-O-Graph**[®]. It is only connected to the pneumatic system with the silicon tube and to the mainboard with a wire-to-board connector.

How to replace:

- Follow the steps of the silicon tube replacement.
- Only the connector shown in Fig. 17 is the right one to connect the valve with the silicon tube. Do not use the other connectors!

Battery contacts:

How to replace:

- Open the housing as shown in Fig. 9.
- Take the pump out of the device.
- Disconnect the wire-to-board connectors on the mainboard and remove the 2 screws (see Fig. 18).

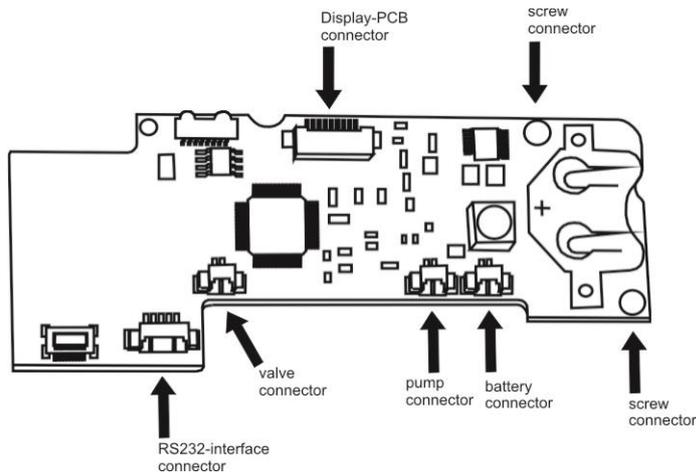


Fig. 18

- Remove the mainboard and disconnect the silicon tube from the pressure sensor.
- Desolder the wires from the battery contacts and press the battery contacts out of the housing as shown in Fig. 19.

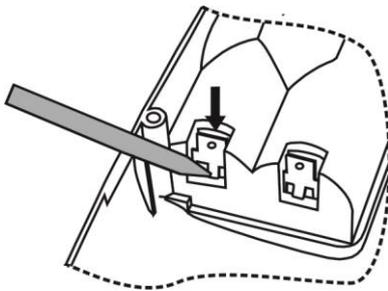


Fig. 19

- Replace the contacts and assemble the **Mobil-O-Graph**[®] in reverse sequence.

Display-PCB:

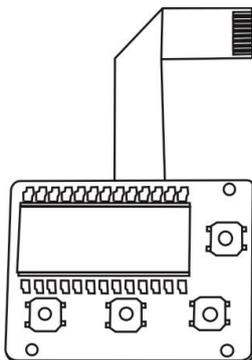


Fig. 20

The display-PCB is connected to the mainboard with a wire-to-board flat cable and fixed in the housing with 3 screws.

How to replace:

- Open the housing as shown in Fig. 9.
- Take the pump out of the device.
- Disconnect the wire-to-board connectors on the mainboard and remove the 2 screws (see Fig. 21)

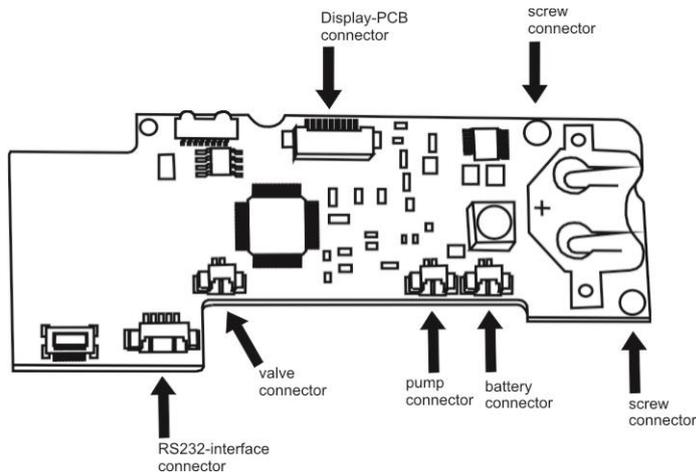


Fig. 21

- Remove the mainboard and disconnect the silicon tube from the pressure sensor.
- Remove the 3 screws from the display board.
- Replace the display board and assemble the **Mobil-O-Graph**[®] in reverse sequence.

Bluetooth-PCB:

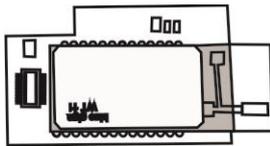


Fig. 22

The Bluetooth PCB is fixed on the mainboard with an electrical board-to-board connector and a double-faced adhesive tape.

How to replace:

- Open the housing as shown in Fig. 5.1.
- Replace the Bluetooth board on the mainboard as shown in Fig. 23.
- Disconnection is facilitated by a careful pull of the Bluetooth PCB.

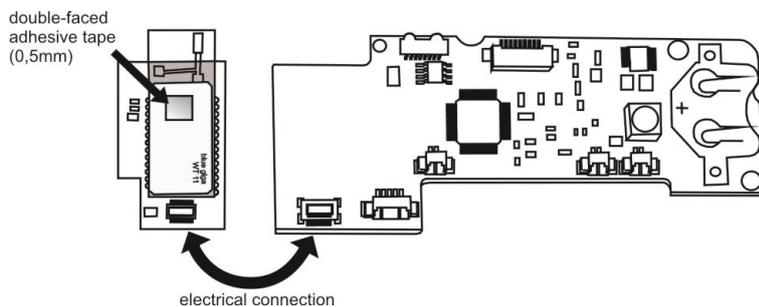
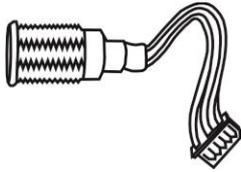


Fig. 23

- Replace the Bluetooth board and assemble the **Mobil-O-Graph**[®] in reverse sequence.

RS232 Interface socket:**Fig. 24**

The RS232 interface socket is assembled at the housing with a screw nut and a circlip. A wire-to-board connector connects the socket to the mainboard.

How to replace:

- Open the housing as shown in Fig. 9.
- Disconnect the wire-to-board connectors on the mainboard.
- Unscrew the screw nut.
- Replace the RS232 interface socket and assemble the **Mobil-O-Graph**[®] in reverse sequence.

7 Circuit and Component Description

7.1 Power Supply

Operation with 2 x AA Accumulators (>1500mAh) or batteries. Voltage range from approximately 3.2 to min. 2.5 Volt.

7.1.1 Voltage on the PCB:

6.0V for analog circuitry, pump und valve: min. 600mA

The DC/DC converter TPS61032PWP supplies an output power of max. 1A at a min. input voltage of 1.8 V, has a power save mode and can be switched on/off via MCU.

Operating range: $V_{in} = \text{min. } 2.4 \text{ V}$ (as well as 1.9 V during pumping) defined in the firmware.

3.3V for display, Bluetooth and RS232: approximately 200mA

The LDO TPS76333 supplies an output power of max. 200mA.

Switched on/off via MCU.

Noise < 10 mVp-p for BT-modules.

3.0V backup for the controller integrated clock (RTC)

A Lithium Battery CR2032 has a capacity of approximately 230mAh and has a durability of approximately 10 years.

At a power consumption of 9 μ A by turn off condition is the capacity enough for 2.5 years, as well as 5.9 years by regular operating.

In case of an empty backup battery, the controller is supplied by the 2 x AA accumulators in order to guarantee even then the function of the appliance.

Additionally the controller voltage is supported by the 2 x AA accumulators during the regular operating to prevent a discharge of the lithium cell.

7.2 Display

LCD with separated Driver

Driver:

PCF8566T, with 24 segments; X-2,3,4 multiplex; 3.3V; 1/3, 1/2 bias; driver control by I²C bus.

Display:

48 segments (X2 multiplex / 24 segments); 3.3V 1/2 bias.

Controller Interface:

I²C.

7.3 Acoustic Signal

SMD miniature speaker F/SMD8585JS with 3V (2~5V) and 80dB.

The frequency is set by the firmware (approximately 787Hz).

To adjust the volume, the operating voltage of 3.3 or 5 V can be selected through a jumper.

7.4 Keyboard

4 SMD-switches (NO) at ports with interrupt.

7.5 Interfaces:

RS232:

Cable connected over **Mobil-O-Graph**[®] data plug-in.

Line driver/receiver MAX3221 with 3.3V supply.

+/- 15kV ESD protection. Max. 250 kbit/s.

Switched on/off via MCU.

Controller interface: UART0

Infrared:

IRDA module:

TFDU4100 with 3.3V and open collector IR-Emitter.

Encoder/Decoder:

TIR1000 standalone CODEC with 1200bps to 115kbps.

Switched on/off via MCU.

Controller interface:

UART0

Bluetooth:

Plug-in module (20 Pin; RM 0.5; 3mm height, board to board connector).

Optional Bluegiga's WT12(Class2) or WT11(Class1), Bluetooth version 2.0 EDR module. Other Modules with corresponding firmware employable.

Switched on/off via MCU.

Controller interface:

UART1

7.6 Data storage

I²C EEPROM with 64 kBit (for example CAT24W(F)C64)

1.8 to 5.5 volt read and write operation.

1,000,000 program/erase cycles

100 Year data retention

Switched on/off via MCU.

Controller interface: I²C.

7.7 Analog Circuit

Temperature Compensated Pressure Sensor.

Static Output:

0 to 2.5V for 0 to 375mmHg.

Frequency:

0 to approximately 2Hz during inflation.

0 to approximately 10Hz during deflation (switchable)

Terms taken with the MPXV5050GP, On-Chip signal conditioned, temperature compensated and calibrated.

Dynamic output:

Switchable amplification, to realise output amplitude from 0.5 to 2.5V for 20% to 180% Gain at the simulator (CuffLink).

Frequency:

1 to 9Hz.

1 to 20Hz maybe for a pulse analysis. (switchable)

Realised with the TLV2252 and a corresponding circuit.

In order to avoid overshooting of the dynamic amplifier during the inflation as well as the deflation, the dynamic output must be reset, that means held to 0.0V.

7.8 Safety Circuit

Additional to the safety functions of the firmware, following hardware safety circuits exist:

Pump and valve can only be switched ON over a signal combination with contrary levels. This means each over one port pin combined with a common second port pin.

Via a second controller (MXP430F2001) following functions are observed:

- The analog supply must be switched ON and has a value > 3.7V.

- The static pressure must be below 320 mmHg.
- The ON time of analog circuit must be below 140 seconds.

If one of these requirements is not fulfilled, pump and valve are deactivated and the main controller will be informed.

If the main controller does not respond within 2 Seconds, the device is switched OFF completely and can only be brought back into operation after removal of the 2 x AA accumulators.

7.9 Controller (MCU)

MSP 430F149 (main):

Low Supply-Voltage range, 1.8 V . . . 3.6 V,
Ultra-low-power consumption,
12-Bit A/D converter with internal reference,
2 USARTs (UART0, UART1),
60KB+256B Flash Memory,

MSP 430F2001 (safety):

Low Supply-Voltage range, 1.8 V . . . 3.6 V,
Ultra-low-power consumption,
On-Chip comparator for analog signal,
compare function or slope A/D,
1KB+256B Flash Memory

7.10 Programming

Main Controller:

via JTAG (first programming)
after that via RS232 (Firmware)

Safety Controller:

via JTAG (Spy-Bi-Wire).

The JTAG-ports can be connected on the Circuit Board via a needle adapter.

BT-Modul:

via SPI.

connected via board to board connector.

7.10.1 Transfer standards

Display and data storage:

400kHz I²C

Interface:

TIA/EIA-232-F (PC-cable),

IrDA (Infrared),

Bluetooth v2.0 / Class2/Class1

7.11 Batteries

A complete **Mobil-O-Graph**[®] system includes 4 NiMH accumulators (1.2V with 2000mAh). These accumulators normally deplete if not in use. It is therefore always necessary to recharge the batteries in the special NiMH charger prior to use.

If the device is not used for longer periods, remove the batteries from the recorder to avoid possible battery leakage damage. I.E.M. is not responsible for any accumulator leakage damage.

The **Mobil-O-Graph**[®] has an additional back-up battery (internal Lithium-cell CR2032) for the real time clock. It should be replaced after 2 years during the regular inspection.

If the device is not in use, power consumption under standby-conditions yields 2.5 years life for this battery, as well as 5.9 years when regularly operated.

8 Battery Charger

I.E.M. recommends a special NiMH battery charger supplied with an even amount of NiMH batteries (2 or 4). Read the instruction leaflet supplied with the battery charger. NiMH batteries (1.2V, 2000mAh) are recommended. This type of batteries has the capacity to ensure the necessary power delivery over a 24-hour measurement period.

NiMH batteries have following advantages compared to NiCd batteries:

- higher capacity
- longer life expectancy
- no memory effect

The disadvantage of NiMH batteries is their relative high self-discharging (depletion) rate. The battery charger must have a trickle charge function included. This means that after the NiMH's are fully charged they get periodically discharged (a few %) and recharged to maintain the full capacity. It is therefore an advantage to leave the batteries inserted in the battery charger even after they are fully charged.

If the NiMH batteries are not used for a longer period, then it may be necessary to perform three complete charging/discharging cycles to ensure the full capacity.

8.1 Distributors

If battery chargers and batteries other than the I.E.M. recommendations are to be used, then they must be intensively tested to ensure a proper operation. Typical power consumption of the recorder during a manual and an automatic measurement are shown as charts in the appendix F.

Following specifications **must** be met:

- Each charger must be tested separately. This means at least to perform a test charge of discharged batteries 5 times in a row. The charger is then inspected for mechanical and electrical malfunctions. The charged batteries are to be inserted in the recorder and must deliver power for about 300 measurements.
- Each battery type from different manufacturers must be tested if the capacity is sufficient for a 24-hour measurement. It is not enough to trust the specifications printed on the batteries.
- If disposable batteries are to be used we recommend the ENERGIZER, 1.5V, alkaline, AA size batteries. Tests have proved that these batteries come closest to the specifications to insure a 24-h measurement. Alkaline batteries have the disadvantage of having a much larger internal resistance than NiMH or NiCd batteries. At current rates of up to 900mA, at a cuff pressure of 200mmHg, this higher internal resistance causes a reduction of the actual battery voltage. This may cause a power supply problem and 'bAtt' to be displayed on the LCD.

9 Validation

The **Mobil-O-Graph**[®] has been thoroughly validated in numerous technical tests according to international standards and in clinical validations.

9.1 General

All technical standards applicable to the system have been taken into account while testing the **Mobil-O-Graph**[®] for its initial CE-certification for the European market. The device successfully passed all applicable tests, particularly according to the following standards:

EN 1060-1	Non-invasive sphygmomanometers, Part 1: General requirements
EN 1060-3	Non-invasive sphygmomanometers, Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
EN 60601-1	Medical electrical equipment; Part 1: General requirements for safety
EN 60601-1-2	Medical electrical equipment; Part 1: 2. Collateral standard: Electromagnetic compatibility; requirements and tests
EN 60601-2-30	Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

9.2 Quality Certification

The **Mobil-O-Graph**[®] system has passed the requirements to bear the CE mark CE0044 with our Notified Body TÜV Nord. This means that the **Mobil-O-Graph**[®] system fully meets the requirements of the European Medical Device Directive 93/42/EEC.

10 Error codes

Mobil-O-Graph®, recorder software version 20 (06.12.2007)

The recorder's internal software has 10 built-in error codes that are designed to provide quick information on the cause of any problem. The codes will appear in the LCD.

Error code Err 5 will appear as "**bAtt**" on the display

Table 10.1: List of Error Codes

MOB Display	MOB iEr *1	MOB internal Error	Description
E001	004	ERR_04_uiPulseNRZero	After 2 sec. the pulse have not reach the falling level
	007	ERR_07_divByZero1	At no pressure level was the heard frequency in the selected area or parable side open at the top (upside down)
	008	ERR_08_noCalcEnvelope	Parabola could not be calculated
	028	ERR_28_wrongEepromData	Wrong data in the EEPROM
E002	001	ERR_01_missingPuls	Missing pulse
	002	ERR_02_uiPulseTooLong	Pulse-basis-width bigger as in 'MAX_BEAT_WIDTH' defined
	003	ERR_03_uiPulseTooShort	Pulse-basis-width shorter as in 'MAX_BEAT_WIDTH' defined
	020	ERR_20_DiffPressInMeas	At deflate the pressure increase significant (strong moving)
E003	019	ERR_19_wrongPulse	At more than 3 pressure steps was the heard frequency out of the defined area
	021	ERR_21_wrongEnvelope	Difference (minDiffSysDia) between sys and dia value to small
	022	ERR_22_difSysDiaTooShort	Sys pressure is significant bigger as the pump-up pressure
	023	ERR_23_V0Below80perc	Within the hole measurement is occurred a oscillation value that is smaller as start- or End value of the measurement
	024	ERR_24_TPulseBelow70perc	Pulse-basis-width of a value within the hole measurement is smaller as at the start- or end value
	025	ERR_25_pressInconsWAvg	The MAD is out of area, the average value calculated between sys und dia value
	029	ERR_29_diaOutOfRange	Diastolic not in the defined area
	030	ERR_30_sysOutOfRange	Systolic not in the defined area

	031	ERR_31_moreThan40Meas	More steps as selected in MAX_DECREASE_STEPS
	032	ERR_32_uiPulseExceedsVmax	Oscillation to high (limit value)
	037	ERR_37_TLimitExceeded	Measurement time longer as MAX_MEAS_TIME
	043	ERR_43_maxBeatsOnStep	Reach max. pulse value at a pressure step
	045	ERR_45_pressToHigh	Pressure to high

E004	013	ERR_13_commTimeout	Time overflow with the communication
	014	ERR_14_msgNoEtx	Data block without end identifier
	015	ERR_15_msgNoStx	Data block without start identifier
	016	ERR_16_unknownMsgCode	Unknown command
	039	ERR_39_WrongChecksum	Checksum error

E005 *2	017	ERR_17_lowBatt	Battery voltage to low
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E006	046	ERR_46_TCrExeeded	Pressure built up too fast (blockage or bend)
	027	ERR_27_noCuffDetected	Pressure cannot be built sufficiently fast (no cuff or crack)
	072	ERR_72_PRESS_DEC At version 200003	Pressure decrease at pump-up

E007	041	ERR_41_noFreeMem	No memory space in EEPROM
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E008 *3	070	ERR_70_MEAS_INTERRUPT	User abort
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E009	036	ERR_36_autoZeroFault	Error at the automatic zero adjustment or remain pressure bigger than 15 mmHg for more than 10 sec
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	042	ERR_42_SETDCO_TimeOut	Internal oscillator error
	044	ERR_44_osziFault	External oscillator error
	064	ERR_64_ANA_INIT	Error switch ON analogue voltage
	065	ERR_65_PRESS_TOO_HIGH	Pressure to big
	066	ERR_66_WRONG_FUNC	Error at function registration
	067	ERR_67_TIME_OVERFLOW	Analogue voltage to long activate
	068	ERR_68_CRC_ERROR	Error in program code CRC
	069	ERR_69_WATCHDOG_OVL	Watchdog-Overflow
	071	ERR_71_PRESS_ERROR	Pressure circuit unusual
	072	ERR_72_PRESS_DEC To Version: 200002	Pressure decrease at pump-up
	073	ERR_73_LCD_INIT	Error at init of the display

	000	PROTO	Standard measurement with protocol
	100	MANUAL	First measurement via press start key
	101	EVENT	Measurement via event key
	102	TRIGGER	Start measurement with trigger-mode
	103	PRESSED_ON	Device switch ON
	104	PRESSED_OFF	Device switch OFF
	105	ERR_REPEAT	Measurement after a error-measurement
	106	ERGOMETER	Measurement with ergo meter protocol
	123	DAY_NIGHT	Day/Night would be activate and get a switch
	124	NIGHT_OFFWINDOW	Day/Night would be activate and get no switch

*1: Error column MOB_INSPECTOR : Get meas series, Get meas mem

*2: Instead of E005 display "bATT"

*3: Instead of E008 display "-StoP-"

Table 10.2: Other problems that may occur

Symptom	Cause	Solution
The clock does not appear when the Mobil-o-Graph is turned on.	<ol style="list-style-type: none"> 1. There are no batteries in the monitor, or the batteries are empty 2. The monitor has not been used for more than two months 	<ol style="list-style-type: none"> 1. Insert freshly charged batteries. 2. Insert freshly recharged batteries.
You are not able to change the protocol.	<ol style="list-style-type: none"> 1. Readings from previous measurements are still stored in the internal memory. 	<ol style="list-style-type: none"> 3. You must first erase the old measurements from the memory, see chap. 2.3.2 (erase memory)
'bAtt' is displayed on the monitor LCD.	<ol style="list-style-type: none"> 1. You are using normal or NiCd batteries 2. Batteries are not powerful enough. 	<ol style="list-style-type: none"> 4. Use rechargeable NiMH 1.2V 2100 mAh batteries 5. Recharge batteries (If the device then still doesn't work, it has to be sent for repair)
There is a large amount of Error Codes 2 and 3.	<ol style="list-style-type: none"> 1. The cuff is not correctly fitted or it has become twisted. 2. The Patient moves too much during the measurement, causing oscillations that inhibit accurate measurements. 	<ol style="list-style-type: none"> 6. Refit the cuff. Make sure that the cuff is not too tight or too loose. 7. Instruct the patient to remain still during the whole measurement, in particular during the last stage. Arm, Hand and finger movement must be avoided. Careful instruction of the patient is extremely important to ensure a successful evaluation.
No display announcement, recorder gets hot	<ol style="list-style-type: none"> 1. The batteries are inserted in the wrong way (+/- was exchanged) 	<ol style="list-style-type: none"> 8. Re-insert the batteries in the correct way
Measurement series is not transferred to the computer.	<ol style="list-style-type: none"> 1. The PC is not plugged in/switched on 2. The wrong serial port has been selected. 	<ol style="list-style-type: none"> 9. Check all cable connections and fix them securely 10. Make sure to select the correct serial port in your software

11 Technical specifications

Pressure measurement range:	Systolic 60 to 290 mmHg Diastolic 30 to 195 mmHg
Accuracy:	+/- 3 mmHg in the range indicated
Static pressure range:	0 to 300 mmHg
Pulse range:	40 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:	approx. 300 measurements
Operating temperatures:	+10°C to +40°C
Operating humidity:	15% to 90% rH
Storage environment:	-20°C to 50°C and 15% to 95% humidity
Dimensions:	128 x 78 x 27 mm
Weight:	approx. 250 g including batteries
Power supply:	2 NiMH batteries, 1.2 V, min. 1500mAh (AA, Mignon) or 2 alkaline manganese 1.5V batteries, (AA, Mignon)

12 Schematic, Circuit diagrams, Layouts

The basic information is shown on the following pages. All information within this section is strictly confidential, company private and intellectual property. All and any attempt to copy and/or disseminate contents completely or in part to unauthorized parties will be prosecuted.

B1: General product information

Mainboard

PCB: IEM_601

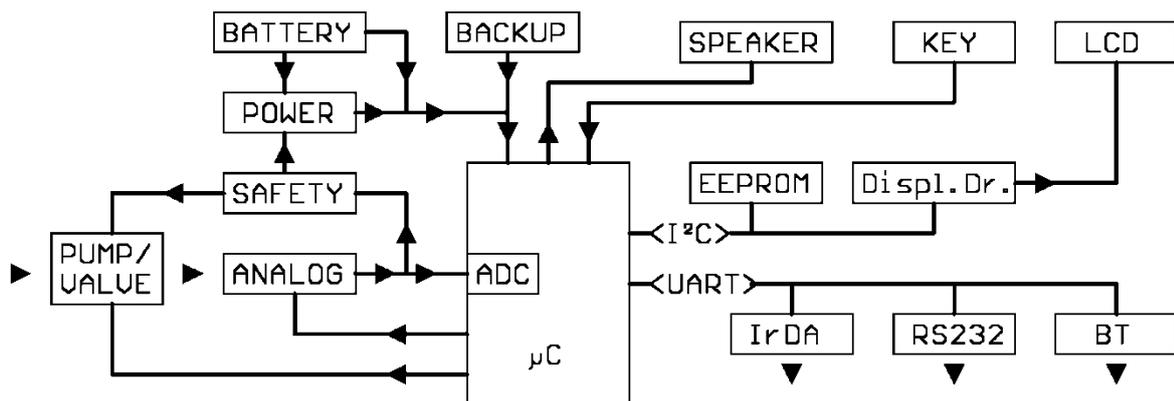
Displayboard

PCB: IEM_602

Bluetooth-board

PCB: IEM_604

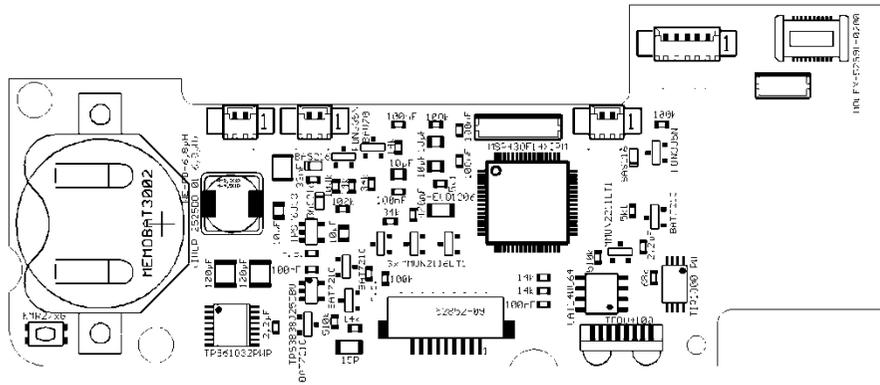
B2: Block diagram



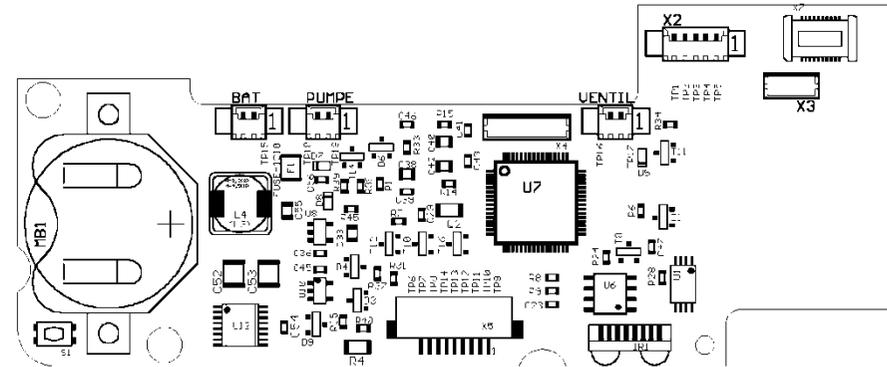
B3: PCBs

Components Mainboard (601)

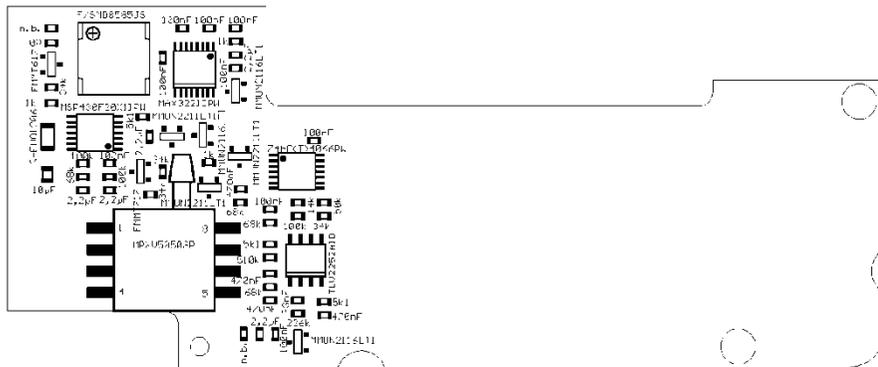
TOP VALUE



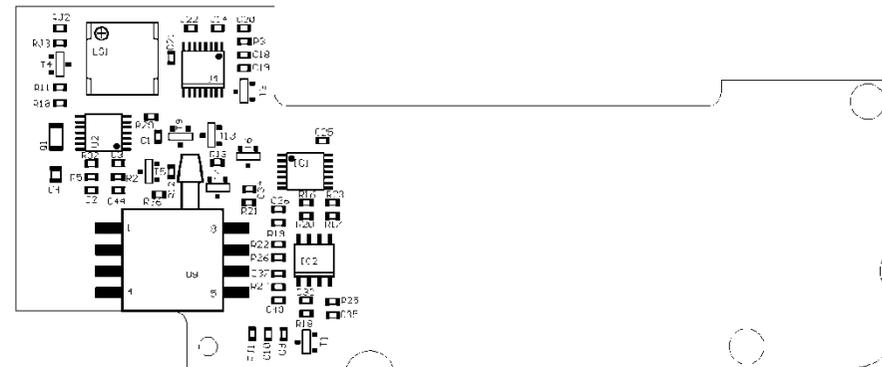
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BOTTOM VALUE

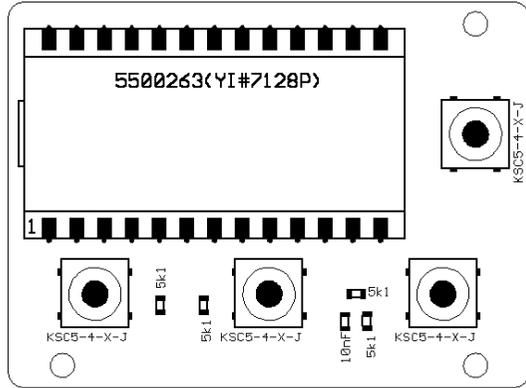


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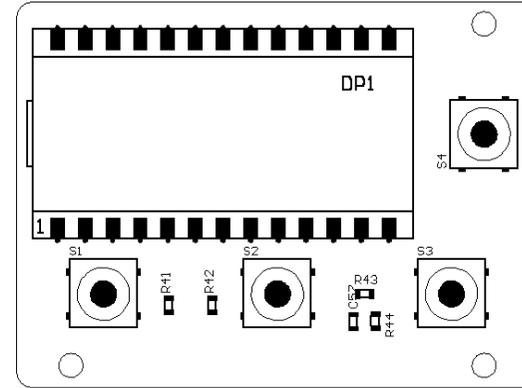


Components Displayboard (602)

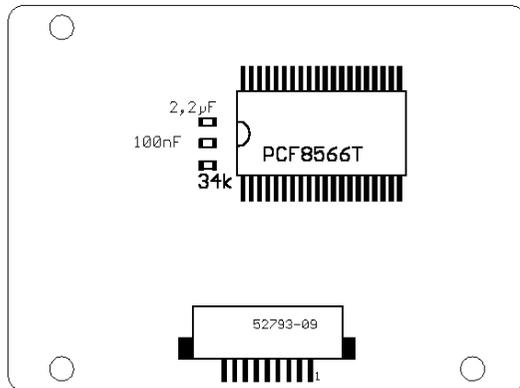
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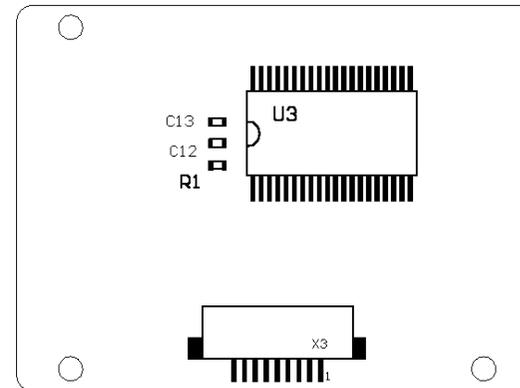
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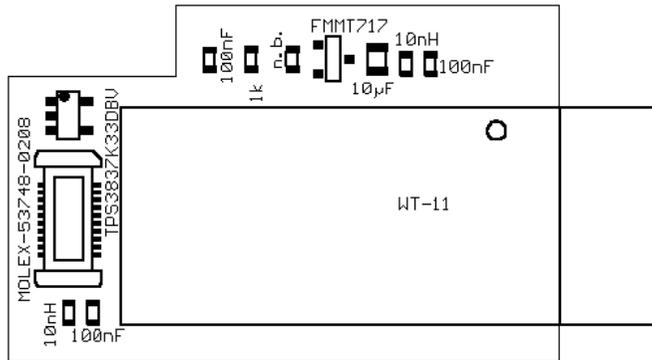


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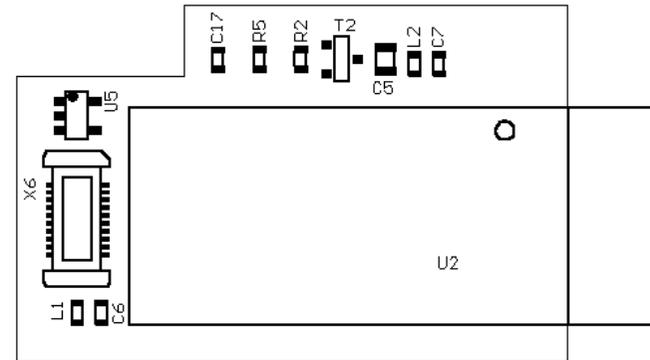


Components Bluetooth-board (604)

TOP VALUE



TOP NAME



The Bluetooth-module used on this PCB is Bluegiga WT11.

Specifications are separate within the Device Master Record.