

STABIL GRAPH

SBPM-CONTROL

*Blood pressure measurement
with the table device -
easy handling,
high accuracy*





*Blood pressure measurement with the table device –
easy handling, high accuracy*

Instruction Manual

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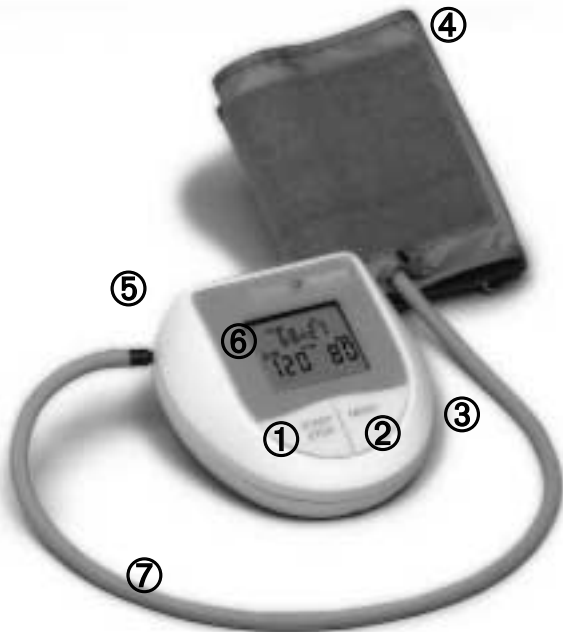
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Contents

1	Overview	2	4.9 Description Of Symbols	8
2	Introduction	3	5 Important Instructions	9
2.1	Preliminary	3	5.1 Important Safety Instructions	9
2.2	Equipment Supplied	3		
2.3	CE-Marking	3	6 Description Of Errors And How To Correct Them	10
2.4	Declaration Of Conformity	3	6.1 Error Messages	10
			6.2 Trouble Shooting	11
3	Application Information	4	7 Maintenance And Care	12
3.1	General Information On Blood Pressure	4	7.1 Care	12
3.2	Indications For Use	4	7.2 Calibration Of The <i>"Stabil-O-Graph®"</i>	12
4	Operation Of The Device	5	8 Warranty And Repair Conditions	13
4.1	Start Of Operation	5	8.1 Warranty	13
4.2	How To Apply The <i>"Stabil-O-Graph®"</i> To Your Upper Arm	5	8.2 Repair	13
4.3	Blood Pressure Measurement And Storing Results	6		
4.4	Evaluation By The Doctor	6	9 Specifications	Cover
4.5	Display Previous And Average Measurements	6		
4.6	Deleting Stored Measurements	7		
4.7	Setting Time And Date	7		
4.8	Reminder Function	7		

1 Overview



- ① Start/Stop-button, described in text as left button
- ② Menu-button, described in text as right button
- ③ Infrared-eye to transmit the stored measured data to the physician's computer (not to be seen on the photo)
- ④ 4. Cuff with cuff connector
- ⑤ Battery compartment below the unit
- ⑥ Display
- ⑦ Connection tube

2.1 Preliminary

With the home blood pressure measuring device **"Stabil-O-Graph®"** you have purchased a first-class system with auto feedback logic, simplest handling and highest reliability. We thank you for your trust and are always available to answer questions about service and the product. Information under www.iem.de

2.2 Equipment Supplied

1. **"Stabil-O-Graph®"** - home blood pressure measurement device with a medium cuff and a connection tube
2. Instruction manual
3. Short Guide
4. Two batteries
5. Warranty card

2.3 CE-Marking

"STABIL-O-GRAPH®" corresponds to the European regulations, which are based on the

Medical-Devices-Directive (MDD 93/42/EEC). The **"Stabil-O-Graph®"** has been validated according to the EC-directive and carries a CE-mark. The device fulfils the regulation of the European Standard for non-invasive blood pressure devices part 1: General Requirements (EN 1060-1) and part 3: Supplementary Requirements for electro mechanical blood pressure measuring systems (EN 1060-3)

2.4 Declaration Of Conformity

Manufacturer:

I.E.M. GmbH

Cockerillstraße 69

D-52222 Stolberg, Germany

I.E.M. GmbH declares that the product **"Stabil-O-Graph®"** is in conformance with the European Directive 93/42/ECC of June 14, 1993 regarding Medical Devices and to the regulatory guidelines and regulations of your country.

Stolberg, November 2002

I.E.M. GmbH

3 Application Information

3.1 General Information On Blood Pressure

The blood pressure fluctuates in the course of the day. The upper norm-value for adults is 140 mmHg for the systolic- and 90 mmHg for the diastolic blood pressure. The threshold value for hypertension in adults is defined by the World Health Organisation (WHO) as 140/90 mmHg. If you measure your blood pressure regularly, you will become more aware about the reactions of your body to different influences (e.g. stress or physical activity) and can consciously adjust to a healthier lifestyle.

Please take your *"Stabil-O-Graph®"* with you on each visit to your physician. If your physician is equipped with our special software, he/ she can evaluate the data stored by you and receives an even better overview about your blood pressure-values.

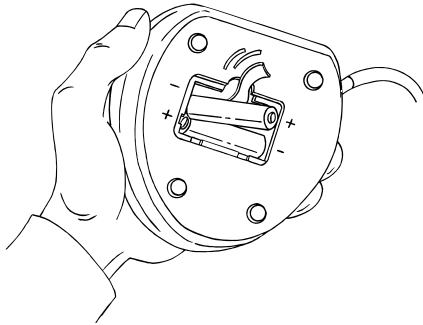
3.2 Indications For Use

- The *"Stabil-O-Graph®"* intended to automatically measure your blood pressure and pulse rate.
- In order to achieve exact measurement results, the device must be placed on a stable surface. The cuff has to be placed on the naked upper arm (see description). Please sit down for the measurement and place your arm relaxed on your thigh.
- The device is suitable for upper arm circumferences of 24 cm to 32 cm while using the medium cuff and of 32 cm to 42 cm while using the large cuff. The cuffs are available from I.E.M. directly or from your supplier.
- The device is only suitable for blood pressure-measurements on adults.
- **Never alter your medication on the basis of the self measured values. The evaluation of the measurements and the basis of the therapy lies exclusively with your physician.**

4 Operation Of The Device

4.1 Start Of Operation

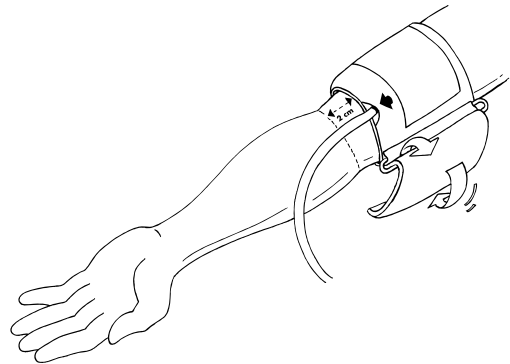
Open the battery compartment on the bottom of the device. Insert the batteries as shown below. Check that the polarity is correct - see label - and that the strip is **under** the batteries.



After the start of the operation, you can set the time and the date (please see "Setting Time And Date"). The "*Stabil-O-Graph*[®]" is now in the operation mode. Always use high quality 1.5V batteries. Please dispose empty batteries according to your local regulations.

4.2 How To Apply The "*Stabil-O-Graph*[®]" To Your Upper Arm

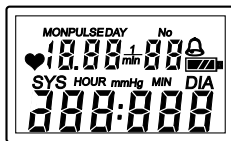
Prepare the cuff as shown in the picture. Please note that the printing is on the outside of the cuff. Pull the cuff till the lower cuff edge is about 2 cm above the elbow (recommended at your left arm). The artery marker arrow should be on the inner side of the elbow pointing down to the hand in order to get correct measurement results. The arm should not be moved during measurement to avoid error measurements



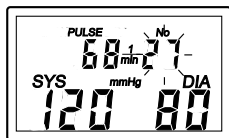
4 Operation Of The Device

4.3 Blood Pressure Measurement and Storing Results

Push the left button briefly once. As long as the button is held down, you should see the following in the display:



The "Stabil-O-Graph[®]" will inflate and will release the air, from the cuff, step by step. After the measurement is completed the display will show the following:



The sequential number of the measurement (example: 27) blinks. After 10 seconds this measurement will be stored under this number. If the left button is pushed once during blinking, the measurement will not be stored.

4.4. Evaluation By The Doctor

The stored measurements can be downloaded to the physicians software via infrared transmission. For more information see the software manual or ask your supplier or physician.

4.5. Display Previous And Average Measurements

First press and hold the right button until the display begins to flash. Now you see the average measurement of the last measurement with a flashing "A". Then press the left button. The previous blood pressure value is displayed followed by the time and date of the recording. You can page backwards to other measurements (max. 50) by repeatedly pressing the left button. Press the right button or wait 30 seconds without pressing any buttons to exit this mode.

The above is only available if measurements have been **stored** in the "Stabil-O-Graph[®]". If not **stored**, the display will then go directly to setting the time, after pressing the right button (see: Setting Time And Date).

4 Operation Of The Device

4.6 Deleting Stored Measurements

If the left button is held down more than 5 seconds, a signal will be heard and the display shows "Clr". If the left button is held down another five seconds, all stored measurements up to this date will be deleted and the time modus will appear again.



Please Note:

Measurements should be taken whilst seated, after 3-5 minutes of relaxation.

4.7. Setting Time And Date




Repeatedly press and hold the right button until MON, DAY, HOUR and MIN start to flash. Then press the left button several times until the minute (MIN) setting is correct. Now press the right button to select hour (HOUR) and then afterwards date (Year, MON, DAY). You can again set the correct numbers with the left button. You can exit this mode, by waiting 30 seconds without pressing any buttons or by pressing the right button until the year disappears.

4.8. Reminder Function

The "*Stabil-O-Graph*[®]" is able to remind you, for instance, to take your prescribed medication. An audible signal will be heard. The setting of the different times (up to 5) can only be done at your physicians office if equipped with the I.E.M. special computer software.

4 Operation Of The Device

4.9 Description Of Symbols

	Operation / Situation	Meaning
	Pulse detected	
SYS [mm / Hg]	Display systolic value	upper value
DIA [mm / Hg]	Display diastolic value	lower value
PULSE [1/min]	Display pulse	number of pulses / minute
	Time of event	sound / blinking as a reminder
HOUR	Display of hour	
MIN	Display of minute	
DAY	Display of day	
MON	Display of month	
	Displayed when battery is empty	change batteries (see 4.1)
Err 01	Error message	see 6.1
No	Number of measurement	
Clr	Delete stored measurements	if the left button is pushed 5 more seconds, all stored data will be deleted
Co	Infrared communication mode	Data download option and reminder function programming possible (is only possible at the physicians computer)

5 Important Instructions

5.1 Important Safety Instructions

- **Caution:**

Should unpleasantness occur during a measurement you should proceed as follows;

- **Counter measures:**

Push the left button to perform a instant cuff deflation. Loosen the cuff and take the device off. Please contact your local service point (see cover page).

Please note:

- If you are suffering from any heart problems, such as cardiac arrhythmia etc. or if you are pregnant, always consult with your physician to determine if using the "**Stabil-O-Graph®**" Blood Pressure Table Device is safe for you.
- Please, also ask your doctor in case you take anticoagulants (e.g. ASS, Marcumar, Coumadin etc.)

- Heavy arteriosclerosis and other circulatory problems, or spasms in the lower arm, may result in erroneous readings.
- The displayed pulse value on the device cannot be used to indicate or control the heart rate of a cardiac pacemaker.
- Never use the device during a shower or a bath. However, should liquid enter the device, then both batteries should be removed from the device instantly and further use of the device must be avoided. Please contact the service department (see cover page).
- The device should not be operated within the area of a spin-tomograph or other highly radiating electronic equipment or MNR.
- The use of components other than delivered with the device can lead to measurement errors. The only exception is changing both batteries.

6 Descriptions Of Errors And How To Correct Them

6.1. Error Messages

<i>Error number</i>	<i>Cause</i>	<i>Possible correction(s)</i>
Err 01	Motion detected	Keep your arm still and then repeat the measurement, compare 6.2, 4.2, 4.6
Err 02	Cuff	a) Apply the cuff correctly (see 4.2) b) The circumference of the medium cuff must be between 24 cm – 32 cm and of the large cuff between 32 cm - 42 cm.
Err 03	System error or (Pneumatic defect)	Stop using the device and contact service
Err 04	Battery error	Change both batteries (see 4.1)

6 Descriptions Of Errors And How To Correct Them

6.2 Trouble Shooting

<i>Problem</i>	<i>Possible solution(s)</i>
The measurement cannot be stopped and the cuff does not deflate instantly when pushing the left button once	Loosen cuff, remove both batteries, stop using the device and contact service.
Left button has been pushed but the measurement does not start (pumping stops early)	Check batteries, change both if necessary
Display shows no symbols	Check batteries, change both if necessary
Display shows battery symbol	Change both batteries
Time and/or date wrong	see 4.7: Setting time and date
Frequent error messages	a) Apply cuff correctly according to section 4.2 b) The circumference of the medium cuff must be between 24 cm - 32 cm and of the large cuff between 32 cm - 42 cm: c) Hold arm still during the whole measurement

7 Maintenance And Care

7.1. Care

If necessary, please only clean the plastic housing and the cuff with a moist cotton cloth.

Important:

Do not wash, immerse in fluid or chemically clean the cuff of the "*Stabil-O-Graph*[®]"!

Batteries do not belong in the household waste! Please dispose the empty batteries according to your environmental regulations.

7.2. Calibration

The device has been calibrated by the manufacturer for a period of 2 years of normal usage. We recommend the device should be checked and recalibrated after 2 years of use. This service may be offered by competent authorities or authorized service centres in accordance with international guidelines for calibration of blood pressure devices. Please contact your service department for instructions.



8 Warranty And Repair Conditions

8.1 Warranty

1. I.E.M. grants for the blood pressure measuring instrument two years of guarantee as from the date of sale. The sales date is to be proved by the warranty card filled out properly and/or by the bill.
2. Defects due to material or faulty manufacturing will be corrected free of charge within the warranty period.
3. After a warranty repair, there will be no prolongation of the guarantee period, neither for the device nor for exchanged components.
4. Following warranty claims are excluded:
 - a) all damages resulting from inappropriate handling, e.g., through not following the operating manual
 - b) all damages resulting from repair by the user or unauthorized third parties
 - c) damages incurred during transport on the way from manufacturer to the consumer or in the case of sending the unit to the service point
 - d) accessories, as those are subject to a normal wear (cuff, batteries etc.)

5. Any liability for direct or indirect damages as a result of a device defect is excluded, even if the device defect is handled under warranty conditions.
6. Changed or manipulated warranty cards will not be accepted by I.E.M. GmbH
7. Further claims, for any reason, are not accepted.

I.E.M. GmbH does not guarantee for the batteries.

8.2 Repair

In case of repairs please fill out the Warranty Card with the correct sender address and error description.

Contact your local supplier for details on the next service point

9 Specifications

Measuring range:	Systolic (SYS): 70 mmHg-260 mmHg Diastolic (DIA): 45 mmHg-180 mmHg Pulse (PULSE): 40-240 (1/min)
Operating temperature:	+50F to +104F (+10°C to +40°C)
Operating humidity:	15% to 90%
Storage temperature:	-4F to 122 F (-20°C to +50°C)
Storage humidity:	15% to 95%
Display range:	pressure: 0 mmHg to 300 mmHg pulse: 40 to 240 (1/min)
Accuracy:	Pressure: ± 3 mmHg in displayed range
Measuring method:	Oscillometric
Cuff size:	Upper arm circumference between 9.45" (24 cm) and 12.6" (32 cm) regular (medium) cuff and between 12.6" (32 cm) and 16.54" (42 cm) large cuff.
Memory:	50 measurements and maximum 5 reminder settings
Display:	Liquid Crystal Display (LCD)
User interaction:	2 buttons: »START/STOP« and »MENU«
Data interface:	Infrared, bi-directional
Power supply:	2 x alkaline 1.5V mignon batteries (AA, LR6)
Housing dimensions:	app. 4.9"x 5.16"x 2" 125 mm x 131 mm x 51 mm (W X L X H)
Weight:	9.57 oz (270 g) incl. batteries

(This Instruction Manual is subject to change without notice)
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