

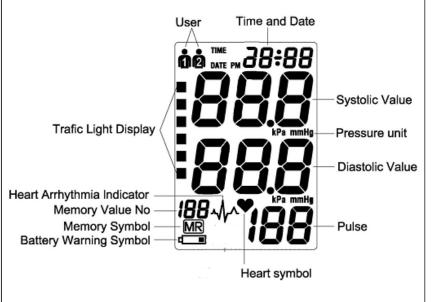
Blood Pressure Monitor Goldline

Instruction Manual



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1. Introduction

1.1. Features of the Automatic Upper Arm Style Goldline Blood Pressure Monitor

The blood-pressure monitor Automatic Upper Arm Style (with integrated time/date display) is a fully automatic, digital blood-pressure measuring device for use on the upper arm, which enables very fast and reliable measurement of the systolic and diastolic blood-pressure as well as the pulse frequency by way of the oscillometric method of measurement.

The device offers very high and clinical tested measurement accuracy and has been designed to provide maximum of user-friendliness.

Before using, please read this instruction manual carefully and keep it in a safe place. For further questions on the subject of blood-pressure and its measurement, please contact your doctor.

Attention!

1.2. Important information about self-measurement

- Substitution of a different component might result in measurement error.
- · Cuff is replaceable only by an original.
- · Do not use on neonatal patients.
- Do not intend to use on pregnant or pre-eclamptic patients
- Keep Product in proper packing. Any wrong use will cause harmful injury to the patient or affect the blood pressure.
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- The application of the cuff over a wound can cause further injury.
- The application of the cuff and its pressurization on any limb where intravascular access or therapy, or an arteriovenous (A-V) shunt is present because of temporary interference to blood flow and could result in injury to the patient.
- Do not let the cuff and its pressurization on the arm on the side of a mastectomy
- Pressurization of the cuff can temporarily cause loss of function if simultaneously used monitoring ME equipment on the same limb.

- Please check that operation of the automated sphygmomanometer does not result in prolonged impairment of patient blood circulation.
- Not intended to be used together with HF surgical equipment.
- Do not forget: self-measurement means control, not diagnosis or treatment. Unusual values
 must always be discussed with your doctor. Under no circumstances should you alter the
 dosages of any drugs prescribed by your doctor.
- · The pulse display is not suitable for checking the frequency of heart pacemakers!
- In cases of cardiac irregularity (Arrhythmia), measurements made with this instrument should only be evaluated after consultation with the doctor.

Electromagnetic interference

The device contains sensitive electronic components (Microcomputer). Therefore, avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave cookers). These can lead to temporary impairment of the measuring accuracy.

2. Important information on the subject of blood-pressure and its measurement

2.1. How does high/low blood-pressure arise?

As your heart beats, it pumps your blood round your body so that your muscles can get all the energy and oxygen they need. To do this, your heart pushes your blood through a network of blood vessels called arteries. As the blood travels through the arteries it pushes against the sides of these blood vessels and the strength of this pushing is called your blood pressure.

As your heart squeezes and pushes your blood through your arteries, your blood pressure goes up. As your heart relaxes, your blood pressure goes down. So, with each heartbeat, your blood pressure will rise to a maximum level and then fall to a minimum level.

2.2. Which values are normal?

Blood pressure is too high if at rest, the diastolic pressure is above 90 mmHg and/or the systolic blood-pressure is over 160 mmHg. In this case, please consult your doctor immediately. Long-term values at this level endanger your health due to the associated advancing damage to the blood

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 Goldline is used exceeds the applicable RF compliance level above, Goldline should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Goldline. *Cover the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances:

Recommended separation distance between portable and mobile RF communications equipment and the Goldline

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

Poted maximum autout nauge	Separation distance according to frequency of transmitter m			
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
or transmitter (vv)	d = 1.2×p ^{1/2}	d = 1.2×p ^{1/2}	d = 2.3×p ^{1/2}	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d inmetres (m) can be determined 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.

Note1:At 80MHz and 800MHz, the separation distance for the higher frequency range applies

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For any further query please contact: - dr@drtrustusa.com

variations on power	40 % U _T (60% dip in		environment. If the user of the upper arm
supply input lines IEC	U _⊤) for 5 cycles		style requires continued operation during
61000-4-11	70 % U _⊤ (30% dip in		power mains interruptions, it is
	U _⊤) for 25 cycles		recommended that Goldline be powered
	<5 % U _T (95% dip in		from an uninterruptible power supply or
	U _⊤) for 5 sec.		a battery.
Power frequency (50/	3 A/m	Not applicable	Not applicable
60 Hz) magnetic field			
IEC 61000-4-8			

Note: U_T is the a.c. mains voltage prior to application of the test level.

Immunity test	IEC60601-1-2 test	IEC60601-1-2	Electromagnetic environment - guidance
ininunity test	level	test level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be
			used no closer to any part of the Goldline, including cables, than
			the recommended separation distance calculated from the
			equation applicable to the frequency of the transmitter.
			Recommend separation distance
			3V
			d = 1.2×p ^{1/2} 80Mhz to 800 MHz
			d = 2.3×p ^{1/2} MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter
Conducted RF IEC	3 Vrms 150 kHz to 80		in watts (W) according to the transmitter manufacturer and d is
61000-4-6	MHz 80% AM (2Hz)	3 Vrms	the recommended separation distance in meters (m).
01000-4-0	WII 12 00 70 74W (21 12)	0 11113	Field strengths from fixed RF transmitters as determined by an
			electromagnetic site survey ⁸ , should be less than the compliance
Radiated RF IEC	3 Vrms 80 MHz to 2.5		level in each frequency range ^b . Interference may occur in the
61000-4-3	GHz 80% AM (2Hz)	3 V/m	vicinity of equipment marked with the following symbol:
	(<u></u>	2 7/111	((<u>@</u>))

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from

vessels in your body.

Should the systolic blood-pressure values lie between 140 mmHg and 160 mmHg and/or the diastolic blood-pressure values lie between 90 mmHg and 100 mmHg, likewise, please consult your doctor. With blood-pressure values that are too low, i.e. systolic values under 100 mmHg and/or diastolic values under 60 mmHg, likewise, please consult your doctor. Even with normal blood-pressure values, a regular self-check of your blood-pressure is recommended. In this way you can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, please keep a record of the level of your blood pressure by carrying out regular self-measurements at specific times of the day. Show these values to your doctor.

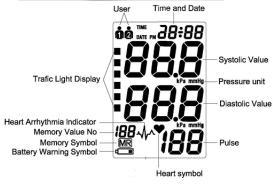
Never use the results of your measurements to alter independently the drug doses prescribed by your doctor.

Table for classifying blood-pressure values (unit: mmHg) according to World Health Organization:

Ra	nge	Systolic	Diastolic	Traffic light	Recommendation
	blood pressure too low	₹100	₽ 60	Yellow-orange	Consult your doctor
1.	blood pressure optimum	100-120	60-80	Green	self-check
2.	blood pressure normal	120-130	80-85	Green	self-check
3.	blood pressure slightly high	130-140	85-90	Yellow-orange	Consult your doctor
4.	blood pressure too high	140-160	90-100	Yellow-orange	Seek medical advice
5.	blood pressure far too high	160-180	100-110	Red	Seek medical advice
6.	blood pressure dangerously high	180 🛊	110 🛨	Red	Urgently seek medical advice!

3. Components of blood-pressure Monitor





14. Manufacturer's Declaration

Goldline is intended for use in the electromagnetic environment specified below. The customer or the user of the Goldline should assure that it is used in such an environment.

Electromagnetic Emissions: (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	Goldline uses RF energy only for internal functions.
		Therefore, this RF emission is extremely weak and there is
		little chance of it creating any kind of interference
		whatsoever with nearby electronic equipment.
RF emissions CISPR 11	Class B	Goldline Is suitable for use in all establishments, including
Harmonic emissions IEC 61000-3-2	Not applicable	domestic establishments and those directly connected to the
Voltage fluctuations/flicker IEC	Not applicable	public low voltage power supply network that supplies
61000-3-3		buildings used for domestic purposes.

Electromagnetic Immunity: (IEC60601-1-2)			
Immunity test	IEC60601-1-2 test	Compliance level	Electromagnetic environment -guidance
	level		
Electrostatic discharge	±6 kV contact	±6 kV contact	Floors should be wood, concrete or
(ESD) IEC 61000-4-2	±8 kV air	±8 kV air	ceramic tile. If floors are covered with
			synthetic material, the relative humidity
			should be at least 30 %.
Electric fast transient/	±2 kV for power supply	Not applicable	Mains power quality should be that of a
burst IEC 61000-4-4	lines		typical commercial or hospital
	±1 kV for input/output		environment.
	lines		
Surge IEC 61000-4-5	±1 kV differential mode	Not applicable	Mains power quality should be that of a
	±2 kV common mode		typical commercial or hospital
			environment.
Voltage dips, short	<5 % U _T (95% dip in	Not applicable	Mains power quality should be that of a
interruptions and voltage	U _⊤ .) for 0.5 cycle		typical commercial or hospital

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13. Technical specifications

Measurement Procedure:	Oscillometric , corresponding to Korotkoff method: Phase I : systolic , Phase V : diastolic		
Display:	Digital display		
Measuring range:	Pressure: 30 to 280 mmHg (in 1 mmHg increment)		
weasuring range.	Pulse: 40 to 200 beat/minute		
Static accuracy:	Pressure: ±3mmHg / Pulse: ±5% of reading		
Measuring resolution :	1mmHg		
Inflation:	Automatic inflation by internal pump		
Memory function:	2 x 120 memories for 2 users (SYS, DIA, Pulse)		
Decompression:	Constant exhaust valve system		
Power source:	4- size "AA" alkaline Batteries		
Rated voltage:	DC 6.0V 4.0W (direct current)		
Operation temperature:	5~40°C/41~104°F		
Operation humidity:	15%~85%RH maximum		
Storage temperature:	-20~60°C/14~131°F		
Storage humidity:	15%~95%RH maximum		
Dimensions :	136×113×65±1.0 mm		
Weight:	505g±5g (including batteries and cuff)		
Cuff pressure display range:	0~299mmHg/0~39.9kPa		
Electrical shock protection:	Internal power unit		
Safety classifications:	Type B equipment		
Mode of operation:	Continuous operation		
Protection against ingress of water:	IP22		
Accessories:	M-L-size Cuff , 4 "AA" batteries, instruction manual ,		

Notice: - Adapter must comply with En60601-1, EN60601-1-2



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4. Operation

4.1. Inserting the batteries

a) Insert the batteries (4 x size AA 1.5V), thereby observing the indicated polarity.

- b) If the battery power reduces less than 20%, battery warning icon appears.
- c) If the batteries are empty, battery warning icon appears indicating immediate replacement

Attention! •After the battery warning icon appears, the device is blocked until the batteries have been replaced.

- Please use «AA» Long-Life or Alkaline1.5V Batteries.
- Please remove the batteries from the device, if the blood-pressure monitor is left unused for long periods,

4.2 User Selection

This advanced blood pressure monitor allows you to track blood pressure readings for 2 individuals independently:-

- 1) Before measurement, make sure you set the user no. for the intended user. The unit can track results for 2 individuals (User 1, User 2).
- 2) Press the TIME button for atleast 3 seconds. The display now indicates the set user. To confirm, press ON/OFF button.
- 3) Click the MEMORY button to select User 2.
- 4) We suggest the first person to take their pressure to be User 1.

4.3. Language selection & Time / Date setting

Language Selection

User can select either of the two languages i.e. English & Hindi, if talking required. Else user can mute the unit.

- 1) Press & hold On/Off button for 3 seconds. Default Language 1(Language English) will appear.
- 2) To change language to Language 2 (Hindi), press memory button one time. Press this button twice to mute. To go back to English press setting button.

Setting the time, date

This blood-pressure monitor incorporates an integrated clock with date display. This has the advantage, that at each measurement procedure, not only the blood-pressure values are stored, but also the exact moment of the measurement. After new batteries have been inserted, the clock begins to run from the following setting: 2010-06-20 09:30 o'clock. You must then re-enter the date and current time. For this, please proceed as follows.

- Press the TIME button for at least 3 seconds firstly, user icon will blink. Then press TIME button
 again, the display now indicates the set year, during which the four characters blink.
- 2. The correct year can be entered by pressing the MEMORY button
- Press the TIME button again. The display now switches to the current date, during which the first character (month) blinks.
- 4. The corresponding month can now be entered by pressing the MEMORY button.
- 5. Press the TIME button again. The last two characters (day) are now blinking
- 6. The corresponding day can now be entered by pressing the MEMORY button.
- Press the TIME button again. The display now switches to the current time, during which the first character (Hour) blinks
- 8. The corresponding hour can now be entered by pressing the MEMORY button.
- 9. Press the TIME button again. The last two characters (Minutes) now blink.
- 10. The exact time can now be entered by pressing the MEMORY button
- 11. Press TIME button (or TIME / DATE or TIME): the unit of measurement will flash.
- 12. Press the "MEMORY to set the unit of measurement (mmHg or kPa)
- 13. Once you have done the settings, press the TIME button (or TIME / DATE or TIME). The setting is confirmed and the clock starts running.
- 14. Now after all settings have been made, press the TIME button once again. The date is briefly

12. Remark:

A	Some electrical and electrical equipments forbid to abandon and disposal at will	€ 0197	Announcement number institutions
س	Manufacturer's name and address	ॐ	Reading Instruction Book before use
03	Not applicable for babies	†	Type B equipment
	Cuff Connector	$\bigcirc \bullet \oplus$	AC/DC Adapter
\triangle	Attention, consult accompanying documents	EC REP	Wellkang Tech Consulting Suite B ,29 Harley Street, LONDON W1G 9QR ,United Kingdom
*	Keep Dry		

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11. Reference to Standards

Device standard: Device corresponds to the requirements of the European standard for non-invasive bloodpressure monitor

IEC60601-1-6:2010+A1:2013/ EN60601-1-6:2010+A1:2015

IEC60601-1:2015+A1:2012/EN60601-1:2006+A11:2011+A1:2013+A12:2014

IEC60601-1-2:2014/ EN60601-1-2:2015

IEC/EN60601-1-11:2015

IEC80601-2-30:2009+A1:2013/EN80601-2-30:2010+A1:2015

EN1060-4 - clinical investigation

ANSI / AAMI SP10, NIBP,

Electrical compatibility: Device fulfils the stipulations of the

IEC/EN 60601-1,

IEC/EN 60601-1-2

The stipulations of the EU-Guidelines 93/42/EEC for Medical Products Class IIa have been fulfilled.

displayed and then the time. The input is now confirmed and the clock begins to run.

Eurther Information

With each press of the button (TIME, MEMORY) one input is made (e.g. switching over from hours to minutes mode, or altering the value by +1). However, if you keep the respective button depressed, you can switch more quickly to find the desired value.

5. Carrying out a measurement

5.1. Before the measurement

- Avoid eating, smoking as well as all forms of exertion before the measurement. All these factors influence the
 measurement result. Try and find time to relax by sitting in an armchair in a quiet atmosphere for about ten
 minutes before the measurement.
- . Measure always on the same arm (normally left).
- Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day.

5.2. Common sources of error

Note: Comparable blood-pressure measurements always require the same conditions! These are normally always quiet conditions.

- All efforts by the patient to support the arm can increase the blood-pressure. Make sure you are in a
 comfortable, relaxed position and do not activate any of the muscles in the measurement arm during the
 measurement. Use a cushion for support if necessary.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- · Avoid compression or restriction of the connection tubing.
- · A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the respective arm, which can lead to false results.
 Correctly executed blood-pressure measurements should therefore first be repeated after a 5 minute pause or after the arm has been held up in order to allow the accumulated blood to flow(after at least 3 minutes).

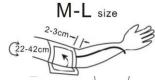
5.3. Fitting the cuff

Insert air connector into air outlet shown in left photo and please make sure the fitting of the air connector is tight completely and proper to avoid air leakage.

a) The distance between the edge of cuff and the elbow should be approx. 2~3cm.



b) Secure the cuff with the Velcro fastener, so that it lies comfortably and not too tight, whereby no space should remain between the cuff and the arm.



- c) Lay the arm on a table, with the palm upwards. Support the arm a little with a rest (cushion), so that the cuff rests at about the same height as the heart. Take care, that the cuff lies free. Remain so for 2 minutes sitting quietly, before beginning with the measurement.
 - d) Let legs uncrossed, feet flat on the floor, back and arm supported.

5.4. Measuring procedure

After the cuff has been appropriately positioned, the measurement can begin:

- a) Press the ON/OFF button, the pump begins to inflate the cuff. In the display, the increasing cuff-pressure is continually displayed.
- b) After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure (large characters) is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink for every pulse beat. The measured systolic and diastolic blood-pressure values as well as

10. Safety, care and disposal

A Safety and protection

- This instrument may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for the damage caused by incorrect application.
- This instrument comprises sensitive components and must be treated with caution. Observe the storage and operating condition described in the "Technical specifications" section!
- Protect it from water and moisture, extreme temperatures, impact and dropping, contamination and dust, direct sunlight, heat and cold.
- The cuffs are sensitive and must be handled with care.
- Only pump up the cuff once fitted.
- Do not use the instrument close to strong electromagnetic fields such as mobile telephones or radio
- Do not use the instrument if you think it is damaged or notice anything unusual.
- If the instrument is not going to be used for a prolonged period the batteries should be removed.
 - Read the additional safety instructions in the individual sections of this booklet. Ensure that children do not use the instrument unsupervised: some parts are small enough to be swallowed.
- Must use the recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety.
- A warning to remove primary batteries if the instruments is not likely to be used for sometime

Instrument care

Clean the instrument only with a soft, dry cloth

Disposal



Batteries and electronic instruments must be disposed off in accordance with the locally applicable regulations, not with domestics waste.

Blood pressure measured differs from those values measured by the doctor.

 Record the daily development of the values and consult your doctor. Please note: Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at the doctor than obtained at home under resting conditions.

8. Care and Maintenance, Recalibration

- a) Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- b) The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- c) Clean the device with a soft, dry cloth. Do not use petrol, thinners or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soap. The cuff must not be washed!
- d) Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.
- e) Never open the device! Otherwise the manufacturer calibration becomes invalid!





9. Battery life:

800 times measurement with 4- size "AA" alkaline Batteries.

the pulse frequency are now displayed.

Example (Fig.): Systole 118, Diastole 73, Pulse 75

The measurement results are displayed, until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off, to save the batteries.

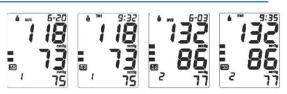


5.5. Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the "ON/OFF" power button can be pressed at any time. The device then immediately lowers the cuff-pressure automatically.

5.6. Memory - storage and recall of the measurements

The blood-pressure monitor automatically stores each of the last 120 measurement values. By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement and the



further last 120 measurements (MR119,MR118...,MR1)can be displayed one after the other

(MR1: Values of the last measurement) (MR2-MR120: Values of the measurement before MR1)

Pay attention that the maximum memory capacity is not exceeded. When the memory is full, the old values are automatically overwritten with new ones.

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5.7. Memory- cancellation of all measurements!

Before you delete all readings stored in the memory, make sure you will not need to refer to the readings at a later date. Keeping a written record is prudent and may provide additional information for your doctor's visit. In order to delete all stored readings, press the MEMORY button for at least 5 seconds, the display will show the symbol «CL» and then release the button. To permanently clear the memory, Press the MEMORY button while «CL» is flashing.



6. Appearance of the Heart Arrhythmia Indicator for early Detection

This symbol Indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal blood pressure – repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to tell your doctor.

7. Error messages /malfunctions

If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed.

Error No.	Possible cause(s)	
ERR 1	No pulse has been detected.	
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: The arm	
	was moved during the Measurement (Artifact).	
ERR 3	The inflation of the cuff takes too long. The cuff is not correctly seated.	
ERR 5	The measured readings indicated an unacceptable difference between systolic	
	and diastolic pressures. Take another reading following direction carefully.	
	Contact you doctor if you continue to get unusual readings.	
ERR8	Pressure in cuff is over 290mmHg	

Further Information - The level of blood-pressure is subject to fluctuations even with healthy people. Important thereby is, that comparable measurements always require the same conditions (Quiet conditions)! If, in spite of observing all these factors, the fluctuations are larger than 15mmHg, and/or you hear irregular puls e tones on several occasions, please consult your doctor. For licensing, the device has been subjected to strict clinical tests, by which the computer program used to measure the blood-pressure values was tested by experienced specialist doctors in Germany. The same computer program is used in every individual device, and has thus also been clinically tested. The manufacture of the devices takes place according to the terms of the European standard for blood-pressure measuring devices (see technical data) you must consult your specialist dealer or chemist if there are technical problems with the blood-pressure instrument. Never attempt to repair the instrument yourself! Any unauthorized opening of the instrument invalidates all guarantee claims!

Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the	1. Check batteries for correct polarity and if necessary insert
instrument is switched on although the	correctly.
batteries are in place.	2. If the display is unusual, re-insert batteries or exchange them.
The device frequently fails to measure	1. Check the positioning of the cuff.
the blood pressure values, or the values	2. Measure the blood-pressure again in peace and quiet under
measured are too low (too high).	observance of the details made under point 5.
Every measurement produces a different	1. Please read the following information and the points listed under
value although the instrument functions	«Common sources of error». Repeat the measurement.
normally and the values displayed are	Please note: Blood pressure fluctuates continually so
normal	successive measurements will show some variability.