GR

Fully Automatic Blood Pressure Monitor for the Upper Arm

Geratherm® easy med



INSTRUCTION MANUAL

GT-868UF

C€0197

Designated use				
Precautionary measures				
Warranty	29			
Information you should know before operating the unit	30			
About the unit	31 32			
Preparation for use Installing/replacing batteries Attaching the pressure cuff Posture during measurement				
Operations Setting the time and date Measuring blood pressure	35 35			
Storing data Recalling data Erasing data	36 37			
Disposal	37			
Care and maintenance	38			
Error messages	40			
Specifications	41			
Quality standard				
Symbol index				
Δnnex 2				

Designated use

This unit uses an oscillometric measurement method in order to measure systolic and diastolic blood pressure, as well as the heart rate.

The measurement is conducted on the upper arm.

All values can be read on an LCD screen.

This unit has been developed for home use and should only be used by adults over 18 years of age with an arm diameter of 23 to 33 cm / 9 to 13 inches.



Precautionary measures

- This manual and the product are not substitutes for visiting the doctor.
 - Neither the information contained herein nor this product may be used to diagnose or treat health problems, or to prescribe drugs. If you have or suspect that you have a medical problem, please seek immediate advice from your doctor.
- Do not conduct any measurements if the temperature is low (below +5 °C) or high (over +40 °C), or if the relative humidity is beyond the range of 15 % to 93 %, as this can lead to inaccurate readings.
- Wait 30 to 45 minutes, before taking a measurement if you have just had a caffeinated drink or a cigarette.
- Relax for at least 5 to 10 minutes before taking a measurement.
- Please wait 3 to 5 minutes between measurements, so that your blood vessels can return to the state they were in prior to measurement. You may have to adapt the waiting time to your personal physiology.
- It is recommended that you use the same arm for each measurement (preferably the left) and take the measurement at about the same time every day.
- Sit down comfortably with your elbows placed on the table and both feet on the ground. Please do not interlock your legs during the measurement.
- Wrap the cuff snug around your upper arm and lay your arm on a flat surface at the same level as your heart.
- Take the measurement at room temperature in a quiet and stress-free environment
- The unit should not be moved or shaken during the measurement. Please do not speak during the measurement.

- Please keep in mind that blood pressure naturally varies depending on the time of day and is affected by many different factors. Blood pressure is usually highest at work and reaches its lowest level during the sleep phase.
- Blood pressure measurements should be assessed by a doctor or trained healthcare professional who is familiar with your medical history. If you use the unit and regularly record the results, please keep your doctor informed with regard to the ongoing changes in your blood pressure.
- If you suffer from a cardiovascular disease (such as atherosclerosis), diabetes, a liver or kidney disease, severe hypertension or peripheral circulatory disorders, etc., please consult your doctor before using this unit.
- This unit is not suitable for use by people with cardiac arrhythmias or pregnant women.
- The blood pressure measurements conducted with this unit are equivalent to measurements obtained by a trained observer in accordance with the values achieved using the cuff/stethoscope auscultation method and are within the specified EN 1060-4 standard limits.
- If the cuff causes any discomfort during the measurement, press the "START/STOP" button to turn off the unit immediately.
- If the pressure is over 300 mmHg and the cuff does not deflate automatically, pull off the Velcro strap to detach the cuff.
- Do not use this appliance on infants, children or persons who cannot express their own intentions.
- To avoid accidental strangulation, keep the product away from children and do not place the hose around the neck.



Precautionary measures

- Measuring too frequently may result in circulatory disorders, which can cause unpleasant sensations such as localised bleeding under the skin or temporary numbness in your arm. These symptoms do not usually last long. However, if you have not recovered after some time, please consult your doctor.
- Please take into consideration the electromagnetic compatibility of the unit (e.g. disruptions to the power supply, radio frequency interference, etc.) see annex.
 Please only use the unit indoors. To avoid inaccurate results due to electromagnetic interference between electrical and electronic equipment, please do not use the unit near mobile phones or microwave ovens. In the case of devices whose maximum power exceeds 2 W, the minimum distance from your blood pressure monitor should be 3.3 metres.
- The unit is not waterproof. Never immerse this instrument in any liquids.
- Do not use the instrument if you think it is damaged or if you notice anything unusual.

Warranty

The warranty for this blood pressure monitor is valid for any error on the part of the manufacturer under normal use for 3 years from the date of purchase. If your unit does not function properly due to defective parts or assembly, we will repair it free of charge.

With the exception of the battery and cuff, all parts of the unit are subject to this warranty. Damage caused by improper handling of your unit is not guaranteed.

We recommend that the accuracy of the unit be checked after 2 years from manufacturing date by an authorized laboratory.

This checking procedure is not a service provided under the warranty.

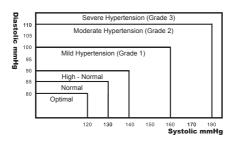
Information you should know before operating the unit

What is blood pressure?

A force is created by the heart as the ventricle forcibly ejects blood into the blood vessels and through the vascular system. Another force is created by the arteries as they resist the blood flow. Blood pressure is the result of these two forces.

Is my blood pressure normal?

See the following blood pressure classification chart released by the WHO (World Health Organization) for evaluation of your blood pressure level.



Classification of blood pressure monitor	Systolic mmHg	Diastolic mmHg	Colour indicator
Optimal	< 120	< 80	green
Normal	120 - 129	80 - 84	green
High - Normal	130 - 139	85 - 89	yellow
Grade 1 Hypertension	140 - 159	90 - 99	red
Grade 2 Hypertension	160 - 179	100 - 109	red
Grade 3 Hypertension	>= 180	>= 110	red

Information you should know before operating the unit

What about low blood pressure?

In general, a lower blood pressure reading is better unless it causes unpleasant symptoms such as fainting and/ or lightheadedness.

What are systolic and diastolic pressures?

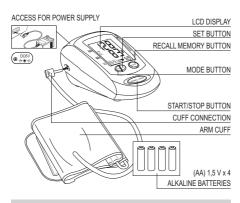
Systolic pressure is the highest pressure at the height of the heart's contraction. Diastolic pressure is the lowest pressure when the heart is resting.

Fluctuation and variation in blood pressure

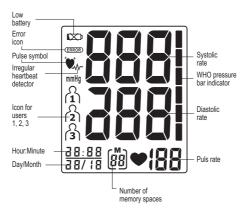
The following factors will influence blood pressure measurement results and cause variations.

Bathing, Breathing, Conversation, Drinking alcohol, Exercise, Moving, Mental tension, Eating, Temperature changes, Thoughts, Smoking etc.

About the unit



The cuff is designed to fit arm diameters between 23 and 33 cm / 9 to 13 inches.



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Preparation for use

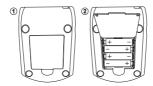
Installing/replacing batteries

- Insert the batteries into the battery compartment matching correct polarities "+" and "-".
- Replace all batteries if the low battery indicator appears :
- Remove the batteries if the unit will not be used for a long period of time.
- REMOVE all of the BATTERIES when utilising an AC adapter.

Note:

It is recommended that the same type of alkaline batteries be used to avoid incompatibility.

Preparation for use

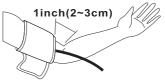




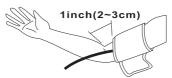
Keep batteries away from small children. Do not throw batteries into fires: they could explode.

Attaching the pressure cuff

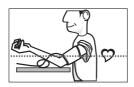
- Wrap the cuff around the left arm. The arm should be bare.
- Fasten the cuff. Don't pull it too strongly or make the cuff too tight. The edge of the cuff should be approximately 1 inch from the crease of your elbow.



3. Attach the cuff on the right arm as shown in the figure if it is not possible to measure on the left arm.



 Sit upright and ensure that the measuring site is at heart level. Relax and retain a natural posture during measurement.



Measure and record blood pressure at the same time every day to establish your blood pressure pattern.



AC adapter

Use the device only with a medical approved stabilized AC adapter (input: 230 V, AC, 50 Hz; output: 6 V, DC, 1 A).



Note:

- No batteries are required during operation using the AC adapter.
- If AC adapter power is interrupted during measurement, the unit must be reset by disconnecting the AC adapter from the unit.
- Only use medical approved adapters that comply with the specifications in this manual. Using other adapters could cause damage your blood pressure monitor.

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Operations

Setting the time and date

- 1. Press the "SET" button to select memory store 1, 2, or 3.
- Press the "MODE" button ("month" starts flashing).Press the "SET" button to set the correct month.
- Press the "MODE" button again ("date" starts flashing). Press the "SET" button to set the correct date.
- Press the "MODE" button again ("hour" starts flashing).
 Press the "SET" button to set the correct hour in 12-hour format.
- Press the "MODE" button again ("minute" starts flashing).Press the "SET" button to set the correct minute.
- Press the "MODE" button again to confirm the time and date.

Measuring blood pressure

- Wrap the cuff around the arm (refer to "Attaching the pressure cuff").
- Sit upright on a chair (refer to "Posture during measurement").
- Press the "SET" button to select a particular memory store number.
- Then press "START/STOP" to start automatic measurement

When taking repeat measurements, be sure to select the same memory store number before pressing "START/STOP".

- 5. The cuff is inflated. When the pulse is detected, the PULSE symbol will start flashing.
- 6. After the measuring procedure has been completed, the blood pressure values (systolic pressure and diastolic pressure) along with the pulse and WHO classification indicator will be shown on the display for 1 minute. After approx. 1 minute without being used, the unit will automatically switch off.
 To interpret the pressurement your may press the
 - To interrupt the measurement, you may press the START/STOP buttons. The cuff will deflate immediately after a button is pressed.

Irregular Heartbeat Detector

If the symbol w-appears, it means the unit has detected an irregular pulse during measurement. If the symbol appears regularly please consult a qualified doctor for professional advice.

Storing data

After each blood pressure measurement, the blood pressure values, pulse rate, time and date will be automatically stored. Each of the three memory stores saves the latest 30 measurements. If more than 30 measurements are saved, the memory will automatically delete the earliest values.

Recalling data:

- Press the "MEMORY" button. A particular memory store will appear on the display.
- 2. Press the "SET" to find the correct memory store.
- Press the "MEMORY". The average value of the last three measurements is shown by the following symbol:
 [A]. If no values have been stored, nothing will appear on the display. The most recently measured value will be displayed first.
- By pressing the "MEMORY" button again you can view each of the saved values in the selected memory store.
- After viewing the saved measurements, press "MEMO-RY" again to switch back to the initial display.
- You can also switch back to the initial display by pressing the "START/STOP" button.

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Storing data

Erasing data:

- 1. Press the "SET" button to select User 1 or 2 or 3.
- 2. Press the "MEMORY" button to enter the Memory Mode.
- Press and hold the "MODE & SET" buttons together, all stored date in the selected user will be erased.
- To confirm the deletion, press the "MEMORY" button and no date should appear.

DISPOSAL



Observe the applicable regulations when disposing of the device and batteries.

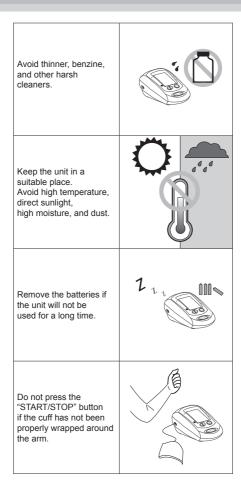
This product must not be disposed of together with domestic waste.

All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner.

Please remove the batteries before disposing of the device/unit.

Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

Do not drop the unit. It is not shock-proof.	
Do not modify or disassemble the unit or the arm cuff.	
Do not twist the arm cuff.	
Do not twist the arm cuff.	



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Specifications

Model No.	GT-868UF	
Display System	Liquid Crystal Display	
Measuring Method	Oscillometric	
Power Source	4 alkaline "AA" type batteries (1.5 V) or AC adapter (Input: 230 V, AC, 50 Hz; Output: 6 V, DC, 1A)	
Measuring Range	Pressure: 0 - 300 mmHg Pulse: 40 - 199 beats per minute	
Accuracy	Pressure: ±3 mmHg Pulse: ±5 %	
Inflation	Automatic	
Deflation	Automatic exhaust valve	
Memory	3 memory stores with 30 storage spaces each = total 90 stored values	
Display	LCD (date/time, pressure and pulse)	
Low Battery Indicator	yes	
Automatic switch-off	approx. 1 minute after last operation	
Battery Life	around 300 operations	
IP Classifi- cation	IP22 (effective against solid foreign objects with a finger; protected against dripping water)	
Cuff Size	23 to 33 cm / 9 to 13 inches	
Operating Environment	+5 °C to +40 °C; RH 15 to 93 % (+41 °F to +104 °F)	
Storage/Trans- port Environ- ment	-25 °C to +70 °C; RH ≤ 93 % (-13 °F to +158 °F)	
Dimensions	110 x 150 x 80 mm (W x D x H)	
Weight	approx. 265 g (including batteries)	

Specifications are subject to change without notice for purposes of product improvement.

Geratherm® is certified in accordance with Council Directive 93/42/EEC andEN ISO 13485 and is entitled to affix the CE-mark C€0197 (Notified Body: TÜV Rheinland LGA Products GmbH).

The blood pressure monitor conforms to

- EN 1060-1 (Non-invasive sphygmomanometers part 1: General requirements) and
- · EN 1060-3 (Non-invasive sphygmomanometers part 3: Supplementary requirements for electromechanical blood pressure measuring systems)
- EN 1060-4 Non-invasive sphygmomanometers, Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphyamomanometers

Symbol index

(3)	Follow the instructions for use	∱ BF	Type BF Equipment
*	Keep dry	LOT	Batch code (mm/yyyy; month/year)
93%	Store at a max. relative humidity of 93 %	SN	Serial number
+70°C	Store between -25 °C and +70 °C		Manufacturer
X			Caution! Read the instruction manual.

Information on electromagnetic compatibility (EMC)

Electronic devices such as PCs and mobile phones can lead to the exposure of medical devices in operation to electromagnetic interference from other devices. This can lead to malfunction of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with any other devices.

The EN 60601-1-2 standard regulates the requirements for EMC (electromagnetic compatibility) and defines the levels of immunity to electromagnetic interference and the maximum electromagnetic emission levels for medical devices.

This blood pressure monitor, which is manufactured by Geratherm Medical AG, complies with the EN 60601-1-2 standard in relation to both immunity and emissions.

However, special precautions should be observed:

please only use the device indoors and not in the vicinity of mobile phones or microwave ovens. In the case of devices whose maximum power exceeds 2 W, the minimum distance from your blood pressure monitor should be 3.3 metres.

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only beused in such environments:

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establish-
Harmonic emissions IEC 61000-3-2	Class A	ments, including domesticestablishments, and those directly connected to the public
Voltage fluctuations / flicker	complies	low-voltage power supply networkthat suppli buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should Compliance

only beused in such environments:

Immunity test	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

Recommended separation distances between portable and mobile RF communication

The device is intended for use in an electromagnetic environment where radiated RF disturbancesare under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:

Rated maximum output power of transmitters in Watt

Seperation distance according to frequency of transmitter / m

	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √P
0.01 0.1 1 10	1.2 3.8	0.12 0.38 1.2 3.8	0.23 0.73 2.3 7.3
100	12	12	23

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity				
The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:				
Immunity test	IEC 60601 – test level	Compliance level	Electromagnetic environment - guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
			Recommended separation distance:	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d= 1.2 √P	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 √P 80 MHz to 800 MHz	
			d = 2.3 \P 800 MHz to 2.5 GHz	
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).	
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. ⁵	
			Interference may occur in the vicinity of equipment marked with the following symbol:	
NOTE 1:	At 80 MHz a	and 800 MHz, the	e higher frequency range applies.	
NOTE 2:	These guidelines may not apply in all situations. Electromagnetic propaga- tion is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration – electromagnetic immunity

- a) Field strengths from fixed transmitters, such as base stations for radio (cellularicordiess) telephones and land mobile radios, anateur radio, All and Fix radio bradcasts at 17 b broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed Fir transmitters, an electromagnetic is usurye should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF Compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



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