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Digital Blood Pressure Monitor for the Upper Arm

Geratherm® desktop 2.0



INSTRUCTION FOR USE

GT-6630

C€0197

Designated Use	30
Precautions	31
Warranty	33
Information You Should Know Before Operating the Unit	34
About the Unit Function Descriptions Explanation of Display Symbols	37 37
Preparation for Use Installing/Replacing Batteries Attaching the Pressure Cuff Measuring Posture	38 39 40
How to Operate the Unit Setting the Clock and Date Measuring Blood Pressure Recalling Memory Values Erasing Memory Values Data Transfer and Analysis via desktop 2.0 Software	41 42 43 44
Care and Maintenance	45
Error Messages	47
Specifications	48
Disposal	49
Quality standard	49
Symbol Index	50
Annex	51

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 and professional use and should only be used by adults over 18 years of age with an arm diameter of $22 \sim 32$ cm / 8.7 - 12.6 inches.

Precautions

- 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 90 %, 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.
- · Place the unit at the level of the heart. Relax your hand. Your palm should be facing up.
- · 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
- The performance of this device can be influenced as severe arrhythmias such as atrial or ventricular premature beats or atrial fibrillation are presented during measurement.
- 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 "POWER" 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.
- 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 quaranteed. 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

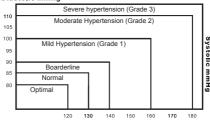
What is blood pressure?

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.

Comparison to WHO recommendations

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

Diastolic mmHg



Blood pressure classifica- tion	Systolic BP mmHG	Diastolic BP mmHg	Color indicator
Optimal	< 120	< 80	6x Green
Normal	120 – 129	80 – 84	3x Green
High – Normal	130 – 139	85 – 89	6x Yellow
Stage 1 Hyperten- sion	140 – 159	90 – 99	2x Red
Stage 2 Hyperten- sion	160 – 179	100 – 109	4x Red
Stage 3 Hyperten- sion	>= 180	>= 110	6x Red

Information You Should Know Before Operating the Unit

What are systolic and diastolic blood pressures?

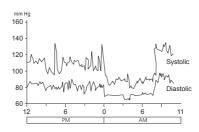
Systolic blood pressure is the highest pressure at the heart's maximum contraction. Diastolic blood pressure is the lowest pressure when the heart is resting.

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.

Fluctuation and variation in blood pressure

The following chart shows possible blood pressure fluctuations during a 24-hour period.

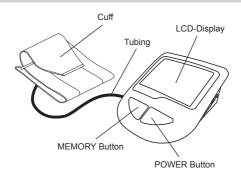


The following factors will influence blood pressure measurement results and cause variations.

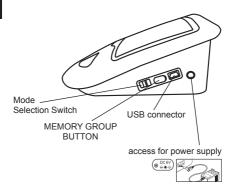
- Bathing
- Drinking alcohol
- Movina
- Eating
- Thinking
- · Smoking etc.

- Conversation
- Exercise
- Mental tension
- Temperature changes
- Breathing

About the Unit



The cuff is designed to fit arm sizes between 22 and 32cm (8.7 to 12.6 inches).



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Function Descriptions

The Geratherm desktop 2.0 has a combination of 2 measuring methods in one measuring procedure – the so-called "Double Check Technology" (DCT). This intelligent measuring method measures the blood pressure values during inflation and deflation and guarantees excellent measuring results and highest accuracy. For rapid measuring results you can switch to the established "fuzzy logic" mode (measurement during release of pressure only).

The blood pressure monitor provides a USB connector plus analysis software, enabling easy transfer to the computer and evaluation of the blood pressure values.

Furthermore Geratherm desktop 2.0 has arrhythmia detection (pulse arrhythmia detection), 50 memory locations for 2 persons, WHO classification (classification of blood pressure values as per World Health Organisation standards) and backlight of display.

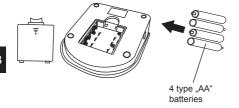
Explanation of Display Symbols Memory Date Low Battery Indicator Clock WHO classification indicator Pulse Indicator Pulse Rate IPD (irregular pulse detection)

Installing/Replacing Batteries

- 1. Insert the batteries into the battery compartment matching correct polarities "+" and "-".
- 2. Replace all batteries if the low battery indicator appears.
- 3. Remove the batteries if the unit will not be used for a long period of time.



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



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

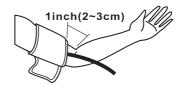
Preparation for Use

Attaching the Pressure Cuff

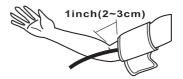
 Wrap the cuff around the left arm. The arm should be bare.



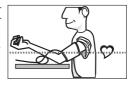
Fasten the cuff. Don't pull it too strongly or make the cuff too tight. The edge of the cuff should be approximately 1 inch from the crease of your elbow.



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 cuff 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 (accessory)

Use the device only with a medical approved stabilized AC adapter (Input: 100 ~ 240 V, AC, 60/50 Hz; Output: 6 V, DC, 800 mA).

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Note:

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

Setting the Clock and Date

With the unit switched off, press the MEMORY button until the display shows a blinking year.

->0 05-

Press the START button to adjust the year while it is blinking.

= X/ 1

Then press the MEMORY button again; the month will appear and blink. Adjust the month using the START button.

*)K(00

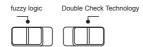
= 1/ Y

Repeat these operations for entering date, hour and minute.

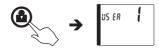
- 8.)4

Measuring Blood Pressure

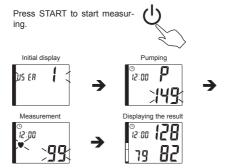
You may choose between 2 measuring modes: fuzzy logic (measurement during deflation) and Double Check Technology (measurement during inflation and deflation). Select prefered measuring mode using the buttons on the side of the unit



Press the MEMORY GROUP button to choose the desired memory group where you would like to store the measuring values (the default setting is memory group number 1).



You may also select or change the memory group by pressing the button after measurement (values are shown on the display).



Operations

When the measurement is completed, the display will show the measured blood pressure values, pulse rate, memory group, date/time and WHO color classification.

Press START to turn off the unit. Otherwise it will turn off automaitcally after about 150 seconds.

As regards the WHO classification, please read on page 34.

Note:
If the symbol " — " appears, it means the unit has detected irregular pulse during measurement. If the symbol appears regularly please consult a qualified physician for professional advice.



Recalling Memory Values

Press the MEMORY GROUP button to choose the desired memory group.



Press MEMORY to recall the last stored measurement value

Press MEMORY again to go to previous memory values.

You may erase one or all memory values.

Erasing one memory value

- Press the MEMORY GROUP button to choose the desired memory group.
- Press and release MEMORY to display the memory values. Press and release MEMORY again to choose the memory value that you wish to erase.
- Press and hold the START button until the display shows "dEL".
- Press and release the START button again. The unit erases the memory value after the third beep.

Erasing all memory values

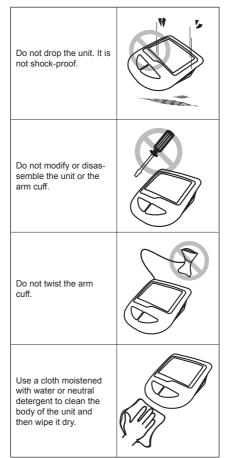
- Press the MEMORY GROUP button to choose the desired memory group.
- Press and release MEMORY to display the memory values.
- Press and hold the START button until the display shows "dEL".
- 4. Press MEMORY and display shows "dEL ALL".
- Press and hold START. The unit erases all memory values after the third beep.

Data Transfer and Analysis via desktop 2.0 Software

The software and the instructions you will find on our homepage via the following link: http://qeratherm.de/diagnostik/downloadbereich/

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Care and Maintenance



Care and Maintenance

Avoid thinner, benzine, and other harsh cleaners. Keep the unit in a suitable place. Avoid high temperature, direct sunlight, high moisture, and dust. Remove the batteries if the unit will not be used for a long time. Do not press the START button if the cuff has not been properly wrapped around the arm.

Messages	Corrections
LL Err	The pressure measured was lower than 20 mm Hg. Please measure again.
UU Err	The pressure measured was higher than 300 mm Hg. Please measure again.
PErr	Pumping error. Please check cuff and try again
rrErr	The pressure can not be measured due to signal noise. Please measure again.
HI	The pumping pressure is higher than 300 mm Hg. Please measure again.
4 50	Low battery. Check and replace the 4 batteries if necessary.

Specifications

Model no. GP-6630

Display System Liquid Crystal Display

Measuring Method Oscillometric method

Inflation Centrifugal micro-pump

Pressure Exhaust Electric solenoid valve

Power Source 4 alkaline "AA" type batteries

(1.5 V) or AC/DC adapter Input: 100 ~ 240 V, AC, 60/50 Hz Output: 6 V, DC, 800 mA

Measuring Range Blood pressure measuring

range: 20 - 300 mm Hg Heart pulse rate range: 40 - 200 pulse beats/min

Accuracy ±3 mm Hg (blood pressure)

±5 % (pulse rate)

IP classification IP 20

Memory 2 x 50 memory values with

date and time displayed

Low Battery Indicator yes

Battery Life around 250 measurements

Auto Power-Off after 150 sec.

 $\label{eq:continuous} \begin{array}{ll} \mbox{Operating Environment} & +5 \ ^{\circ}\mbox{C} - +40 \ ^{\circ}\mbox{C}; \mbox{ RH} < 90 \ \% \\ \mbox{Storage Environment} & -20 \ ^{\circ}\mbox{C} - +55 \ ^{\circ}\mbox{C}; \mbox{ RH} < 90 \ \% \\ \mbox{Dimensions} & 168 \mbox{ mm x 140 mm x 64 mm} \end{array}$

Weight 484 g (incl. batteries)

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

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.



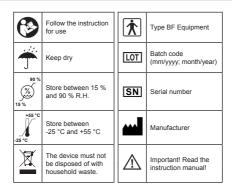
Quality standard

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Geratherm® is certified in accordance with Council Directive 93/42/EEC and EN 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)
- 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 sphygmomanometers





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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 sup- plies 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 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typicalcommercial or hespital 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

	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	0.12	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 in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Annex

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, should be less than the compliance level in each frequency range. ^b
			Interference may occur in the vicinity ofequipment marked with the following symbol:
NOTE 1:			

NOTE 1:

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

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cord-less) telephones and land mobile radios, antateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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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