Digital wrist Blood pressure monitor

Geratherm®

active control

EN

INSTRUCTIONS FOR USE
GT-1215

CE 0197

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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 wrist. 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 a wrist diameter between 13.5 and 21.5 cm.

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.

- If the cuff pressure exceeds 300 mmHg (40 kPa), the air in the cuff is automatically released. If the cuff does not empty when the pressure exceeds 300 mmHg (40 kPa), remove the cuff from your wrist and press the „START“ button to stop the inflation process.

- Before using the unit for the first time, ensure that there is no visible damage to the unit.

- Please use only accessories that have been approved by the manufacturer. Otherwise, damage may be caused to the unit, the user may suffer injury or inaccurate measurements may occur.

- This unit is not suitable for continuous monitoring during medical emergencies or surgery. This unit cannot be used simultaneously with high-frequency surgical devices.

- Please operate the unit under the environmental conditions described in the instructions. Otherwise, the performance and service life the blood pressure monitor will be adversely affected.

- The material of the cuff has been tested and meet the requirements for the biological evaluation of medical devices in accordance with the standards DIN EN ISO 10993-5 and DIN EN ISO 10993-10. The constituent materials do not have the potential to produce any irritation or allergic reactions.

- Dispose of the unit and accessories in accordance with local regulations .

- Consult your doctor before using the unit if you are pregnant, have implanted electrical devices, are suffering from pre-eclampsia, atrial fibrillation or peripheral arterial disease, or if you have undergone intravascular therapy or a mastectomy.

- Keep the unit out of the reach of toddlers, children and pets. The inhalation or swallowing of small parts is dangerous and could be fatal.

- Too frequent and successive measurements may lead to disturbances of the blood circulation and cause injury.

- Do not use the cuff on damaged skin.

⚠ Precautions

- In the event of malfunction, do not attempt to repair the unit yourself. Only permit repairs to be carried out by authorised technicians.
- In the event of unexpected error messages, please contact your dealer.
- For cleaning, please use a soft cloth and a solvent-free cleaning agent.

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Warranty

The warranty for this blood pressure monitor is valid for any error on the part of the manufacturer under normal use for 2 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

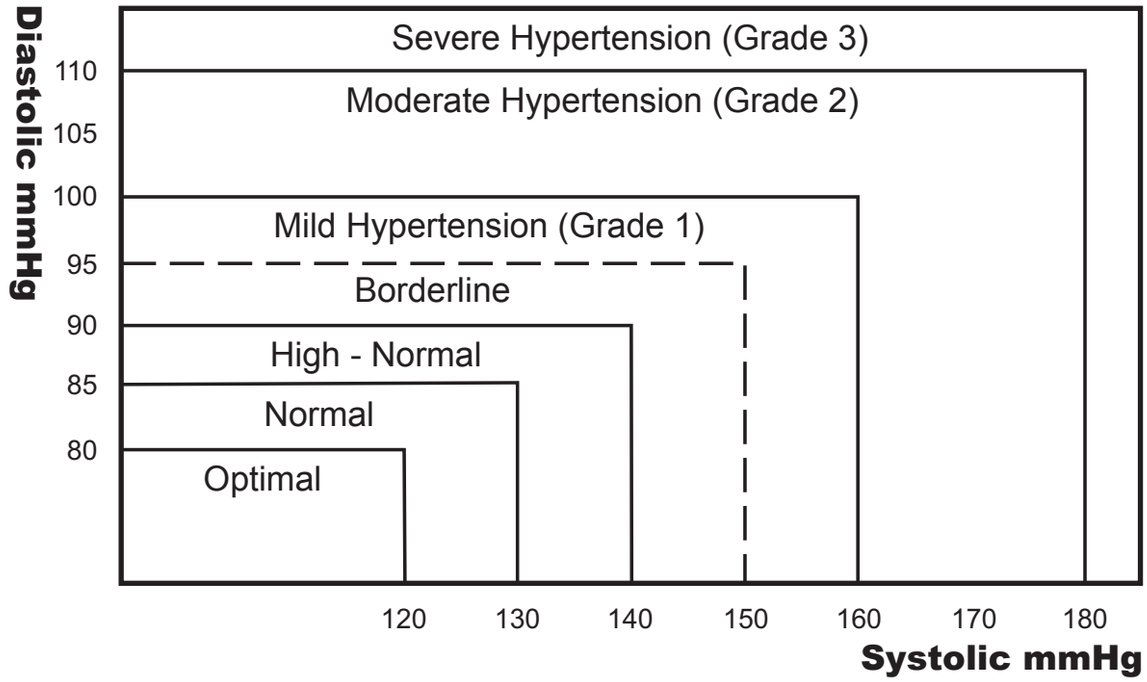
Information You Should Know Before Operating the Unit

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.

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

Information You Should Know Before Operating the Unit

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	green
Grade 1 Hypertension	140 - 159	90 - 99	yellow
Grade 2 Hypertension	160 - 179	100 - 109	orange
Grade 3 Hypertension	>= 180	>= 110	red

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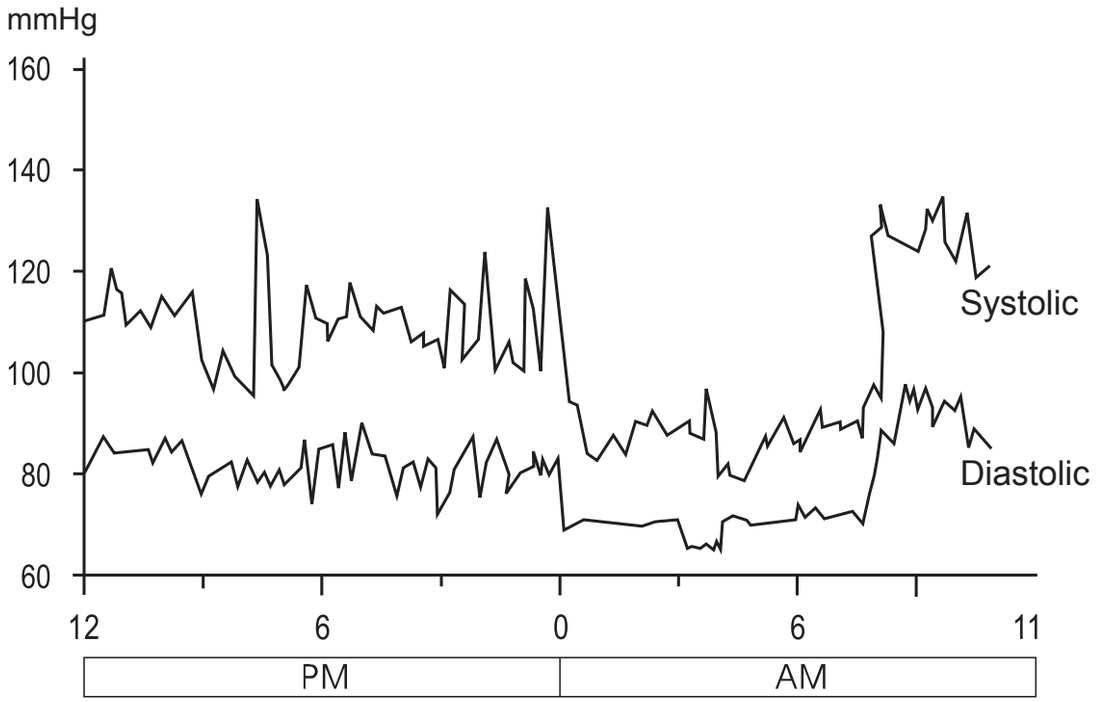
Information You Should Know Before Operating the Unit

What does low blood pressure mean?
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
- Moving
- Meals
- Thoughts
- Conversation
- Exercise
- Stress
- Temperature change
- Smoking etc.

Measurement Principle

This product uses the oscillometric measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure.
Then it starts inflating the cuff. As it does so, the unit detects pressure oscillations generated by the pulsation of the blood flow.

The device compares the longest and the shortest time intervals of detected pulse waves with the mean time interval and then calculates the standard deviation.
Along with the blood pressure reading, the device also shows a symbol (arrhythmia icon) if the heart beat is irregular. (> 25 %)

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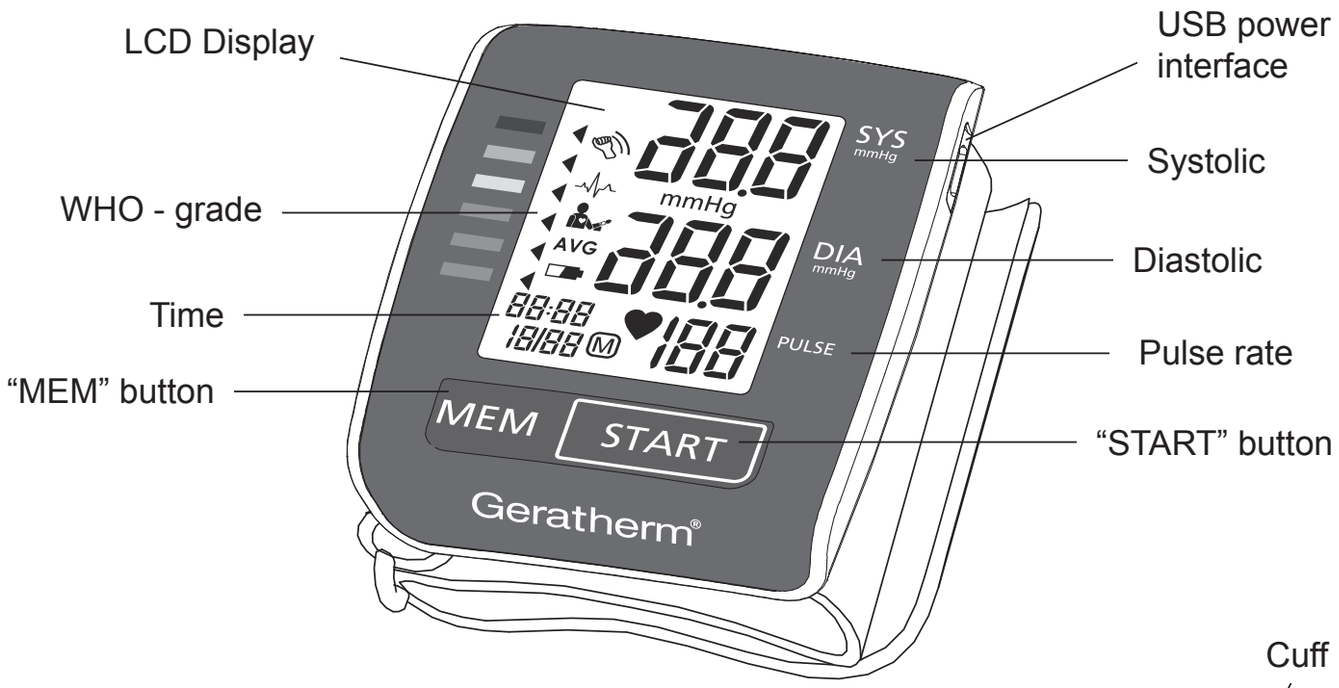
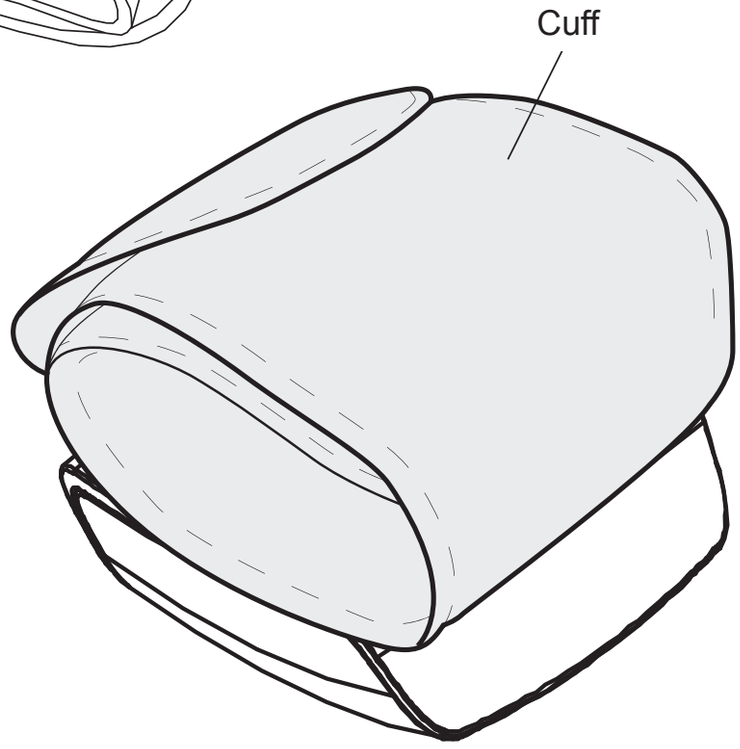
About the Unit

Information about the Device





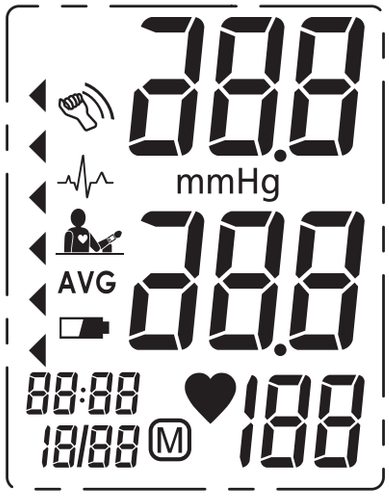
Content:

1. Blood pressure monitor wrist type (GT-1215)
2. User manual
3. USB cable (5 V = 1 A)
4. Storage bag

The cuff is suitable for wrist circumferences between 13.5 and 21.5 cm.

About the Unit

Explanation of the Display



Symbol	Description	Explanation
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
PULSE	Pulse	Pulse/Minute; Beats/ Minute
	Movement detector	Movement will lead to inaccurate readings
	Arrhythmia	Irregular heartbeat Detection
	Position control	Taking up the correct position is necessary for obtaining accurate readings.
AVG	The average value	The average value of the latest 3 blood pressure measurement results
Lo	Low battery	Battery is low and needs to be charged
	WHO Grade	Classification of the reading according to the WHO
88:88 18/88	Current date and time	Month/day, hour/minute
M	Memory	The displayed measurement values is from the memory.
	Heartbeat	Heartbeat detection during the measurement

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Preparation for Use

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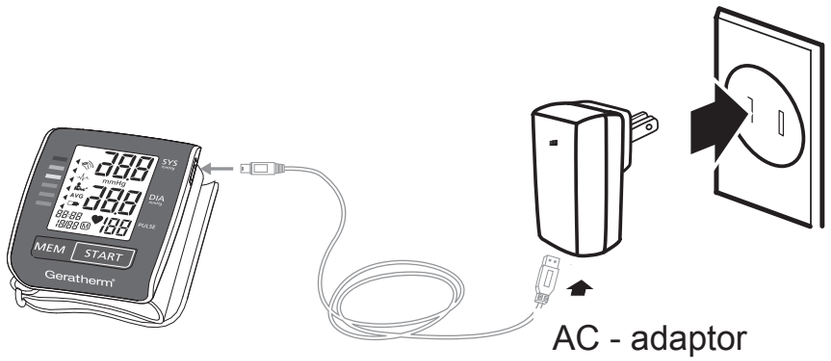
Power Supply and Charge Power

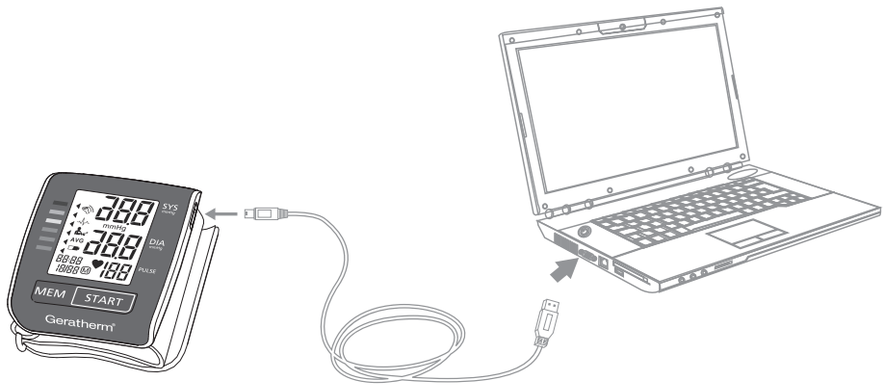
1. The battery of the Geratherm active control is a built-in lithium-ion battery with an electrical charge of 420 mAh.

2. Please use a power adapter with a USB connection (not included) or another source of power with a USB connection and the enclosed USB cable for charging the rechargeable battery, as shown in the following illustrations:

Method 1



Method 2



⚠ **Note:** **Optional Adapter**
(Please use an authorised adapter)
Input: AC 100 - 240 V ~ 50/60 Hz 0,4 A Max
Output: 5 V ⎓ 1000 mA

⚠ **Power needs to be charges under the following circumstances:**

- Lo on the LCD display

Preparation for Use

If you switch on the blood pressure monitor and the LCD display flashes " ", this means that the battery charge is low. Please recharge it in good time. You can still carry out the measurement.

If the LCD displays " LO "means the battery is too low, the blood pressure monitor will turn off automatically, you must charge the power at once.

During the process of charging, the LCD display will display the blinking power level, just like the following pictures:

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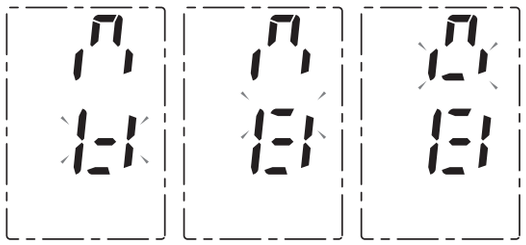
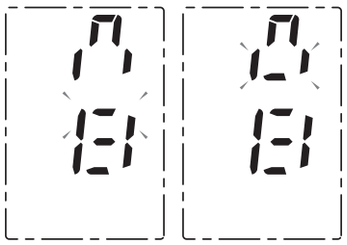
When there is no power, the LCD will displays as the following when it is charging:

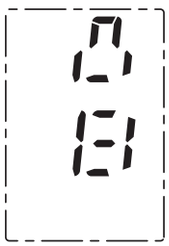


When there is one level of power, the LCD will displays as the following when it is charging:



When there are two levels of power, the LCD will displays as the following when it is charging:

When there are three levels of power, it means the power is full, the LCD will displays as the following when it is charging:



Preparation for Use

⚠ **CAUTION:**

- battery of Geratherm active control is built-in rechargeable lithium-ion battery, please do not attempt to disassemble the blood pressure monitor or force open the built-in battery by the unauthorized maintenance personnel.

- In normal use, the battery can be recharged about 300 times. If the battery fails to recharge or the unit cannot be used normally, please contact your dealer. If you measure your blood pressure three times a day, the unit can be used for up to 25 days without recharging.

- Do not attempt to replace the battery of your blood pressure monitor. The battery is built-in and is not replaceable

- Avoid recharging your blood pressure monitor in extremely high or low ambient temperatures.

- Do not clean the blood pressure monitor during recharging. Always remove the charging unit before cleaning.

Preparation for Use

Activate your blood pressure monitor

Your blood pressure monitor is activated when the date and time are set.

Setting Date and Time

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (time format: 24 h)

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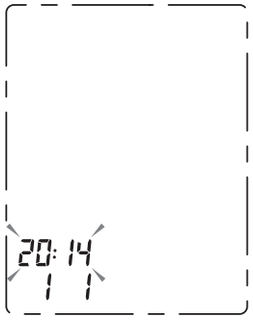
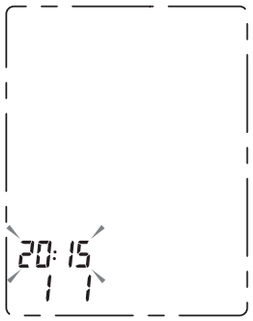
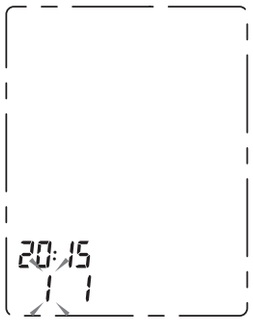
1. When the monitor is off, hold pressing “MEM” button about 3 seconds to enter the mode for year setting.



2. Press “START” button to change the year. Each press will increase the numeral by one in a cycling manner.



3. When you get the right year, press “MEM” button to set down and turn to next step.



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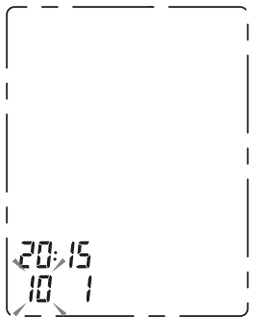
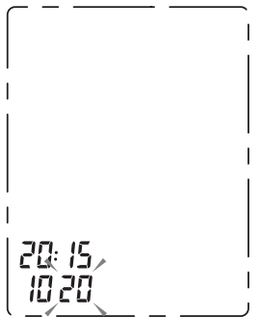
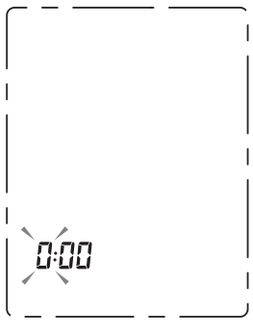
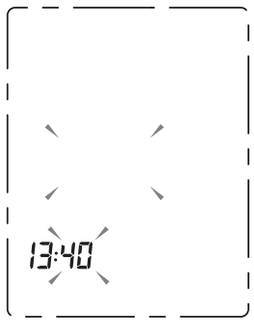
4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].



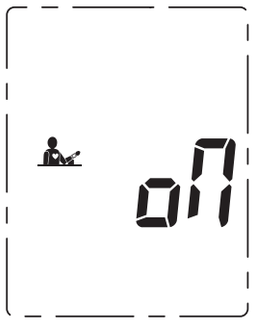


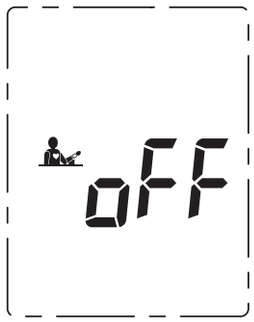
5. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].





6. Repeat steps 2 and 3 to switch position control on or off. After confirming this as described in step 3, all the settings will be successively shown on the display. Then the unit will turn off.



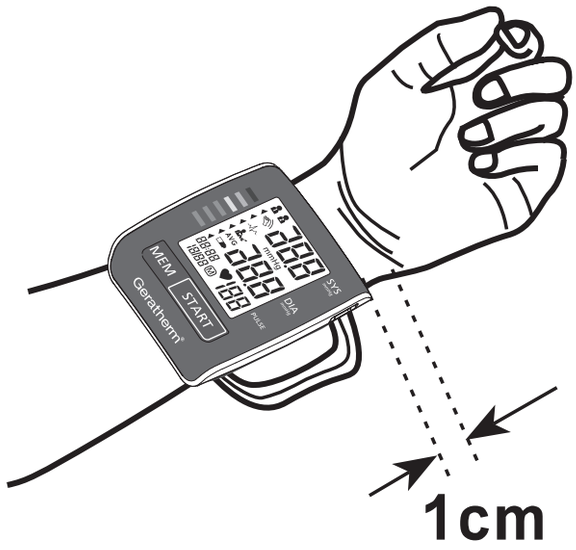


Preparation for Use

Attaching the cuff

1. Wrap the cuff around the bare wrist. The display should face the side of the palm of the hand.

2. Fasten the cuff. Make sure it is not too tight. The cuff‘s upper edge should be approximately 1 cm (0.39 inch) from the palm line.



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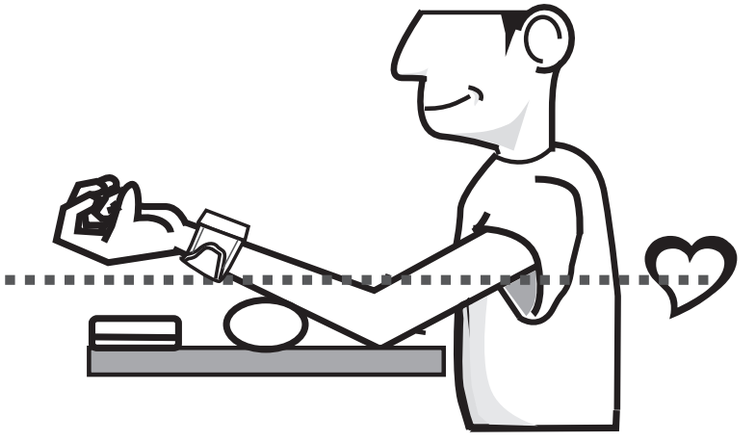
Measuring posture

1. Sit upright and position your lower arm in such a way that the unit is at heart level. Relax and retain a natural posture during measurement.

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

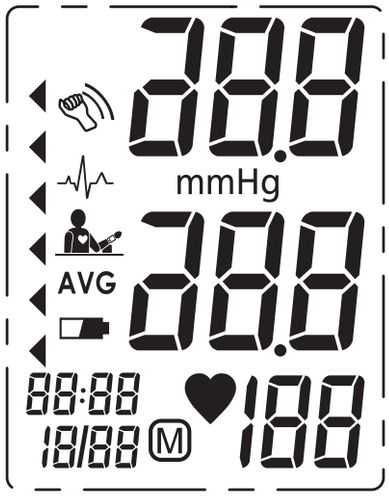


How to Operate the Unit

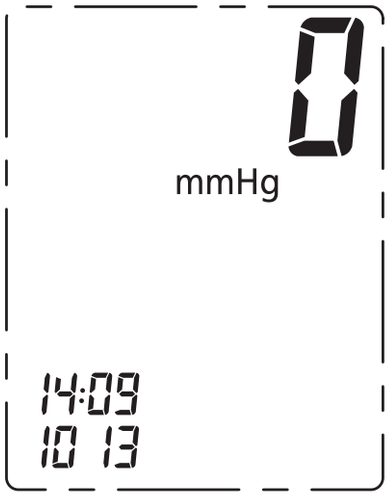
Measuring Blood Pressure

1. When the monitor is off, press the “START” button to turn on the monitor, and it will finish the whole measurement.

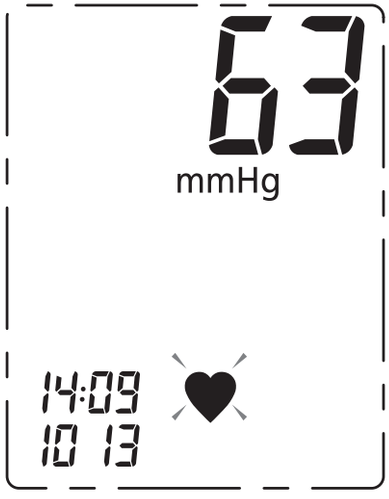
LCD display



0 – value is shown



Inflating and measuring

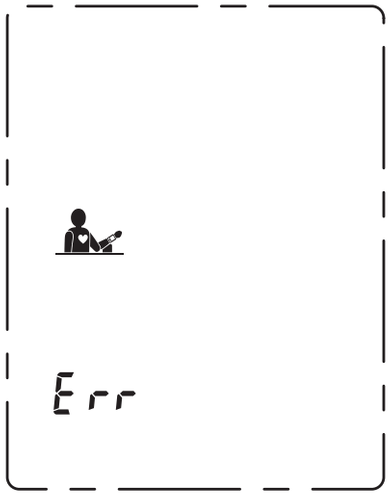


Results are displayed and stored in the memory

2. As soon as the measurement is completed, the blood pressure and pulse readings appear on the display. Press the “START” button to switch off the unit. Otherwise, the unit will switch off automatically after one minute.

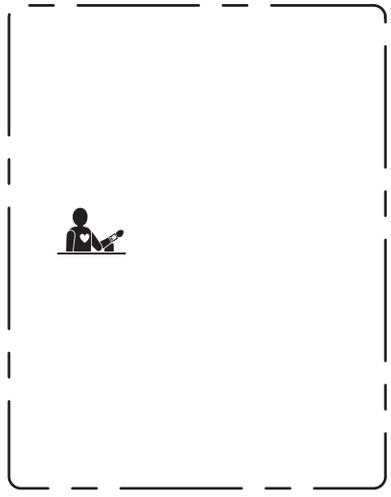
⚠ Note:

If you have turned on the Position Control function, once the measurement starts, the blood pressure monitor will detect the gestrure first. The wrist must be between the angle of 30° and 45°. If the position is out of this angle, the measurement will not start and the display will show Symbol **+ ERR** until you have the correct position.



⚠ Note:

If you have the correct position, the display will show for about 3 seconds, and then continue with the measurement.



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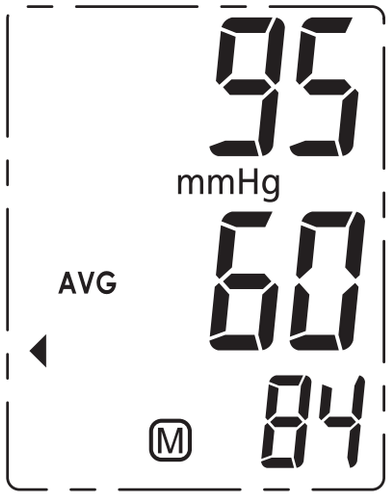
How to Operate the Unit

Retrieving Readings

1. When the monitor is off, please press “MEM” button to show the average value of the latest three records.
   (**Note:** If the records are less than 3 groups, the LCD will display the recent record instead.)



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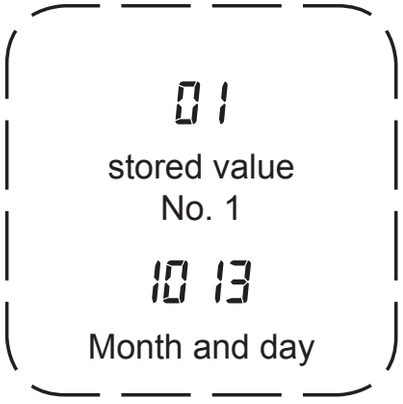
⚠ **Note:**
The device can record 60 measurements.

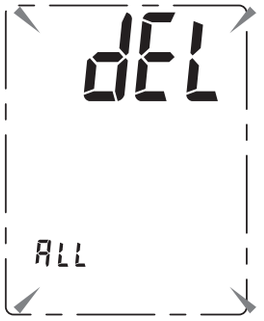
2. By pressing again on the “MEM” button, all stored readings can be retrieved. The number of the stored reading is shown in the bottom left-hand corner. This appears alternately with the time when the reading was taken. The date is shown underneath.

⚠ The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record is dropped from the list.



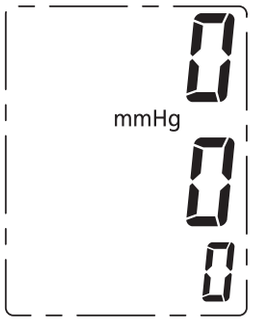
Deleting Readings

1. Hold pressing “MEM” button for 3 seconds when the monitor is in memory mode, the display will show “dEL ALL” (“delete all”) .



2. Press “MEM” button to confirm deleting and the monitor will display “dEL dOnE” (”deletion done”) and then turn off.

3. If there is no record press “MEM” button, the LCD will display “0”.



⚠ Note:
To exit out of delete mode without deleting any records, press “START” button before pressing “MEM“ button to confirm any delete commands.

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Care and Maintenance

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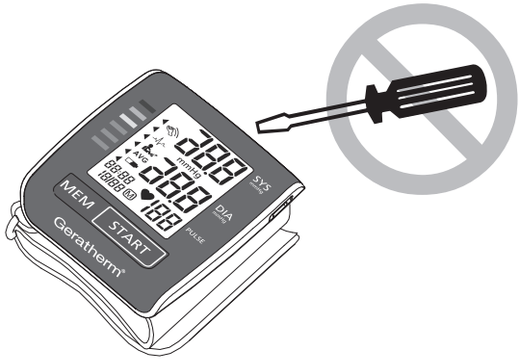
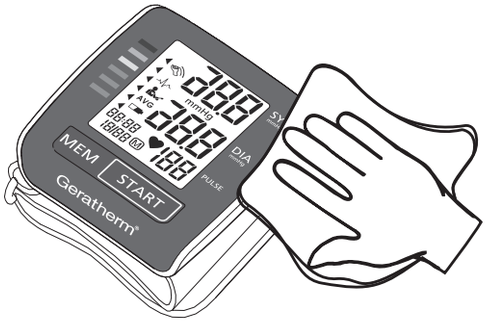
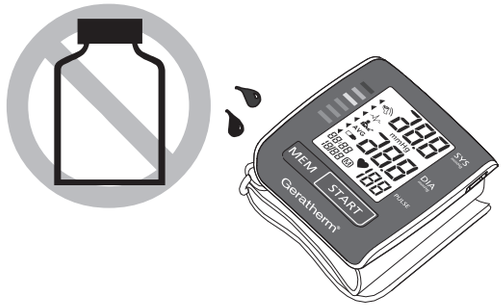
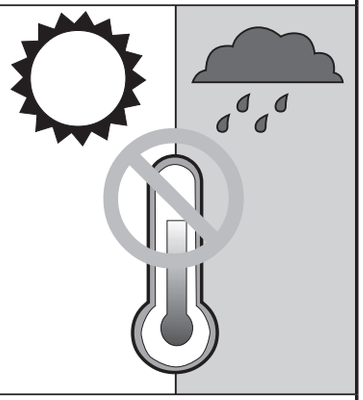
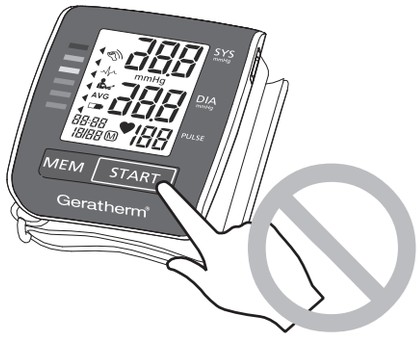
Do not drop the unit.	
Do not modify or disassemble the unit or the cuff.	
Do not twist the cuff.	
Use a cloth moistened with water or neutral detergent to clean the body of the unit and then wipe it dry.	

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.	
Do not press the “START” button until the cuff has been properly fastened on the wrist.	

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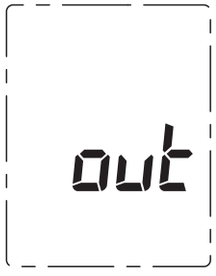
Error messages

Problem	Display symbol	Cause	Solution
No power	Display is dim or will not light up	The power is exhausted	Charge the power
Low battery		The power is low	Charge battery
No display	There is no display when you press any buttons	Unit is not activated.	Press and hold “MEM” button to log out of the shipping mode
Error massage	E 3	The cuff is not properly fastened or pressure in the cuff is too high.	Rest for a short time, then re-fasten the cuff and measure your blood pressure again.
	E10 or E11	The unit has detected movement or pulse rate is too low.	Relax for a moment and then measure again
	E20	The measurement process does not detect the pulse signal	Loosen the clothing on the arm and then measure again
	E21	The measuring process was not successful.	Relax for a moment and then measure again
	EExx	A calibration error occurred	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.
		Out of range measurement	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

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Specifications

Model no.	GT-1215
Power supply	3.7 V 420 mAH Built-in rechargeable lithium-ion battery
Display mode	Digital LCD Display V.A. 44.8 mm x 35.6 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mm Hg ~ 300 mmHg (0 kPa ~ 40 kPa) Measurement pressure: SYS: 60 mmHg ~ 230 mmHg (8.0 kPa ~ 30.7 kPa) DIA: 40 mmHg ~ 130 mmHg (5.3 kPa ~ 17.3 kPa) Pulse value: (40 - 199) beat/minute
Accuracy	Pressure: ±3 mmHg (0.4 kPa) Pulse value: ±5 %
Normal working condition	+5 °C to +40 °C Relative humidity ≤ 85 % RH Air pressure: 80 kPa - 106 kPa
Storage & transportation condition	Temperature: -20 °C to 60 °C Relative humidity: 10 % RH to 93 % RH
Cuff size	13.5 cm ~ 21.5 cm
Weight	106 g (including the cuff)
External dimensions	approx. 84 mm x 70 mm x 40 mm
Attachment	USB cable, storage bag, user manual
Degree of protection	IP22
Device classification	Battery mode: with built-in lithium-ion rechargeable battery

Subject to changes in the interests of technical progress.

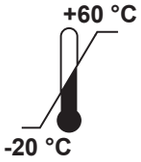
Quality Standard

Geratherm® is certified in accordance with Council Directive 93/42/EEC and EN ISO 13485 and is entitled to affix the CE-mark CE0197 (Notified Body: TÜV Rheinland LGA Products GmbH).

The blood pressure monitor conforms to:

Risk management	ISO/EN 14971 Medical devices - Application of risk management to medical devices
Labeling	EN 980 Symbols for use in the labelling of medical devices
User manual	EN 1041 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1+A1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	EN ISO 81060-1 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1) EN 1060-3+A2 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	DIN EN ISO 81060-2 Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type (ISO 81060-2)
Usability	IEC/EN 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304+AC Medical device software - Software life cycle processes

Symbol Index

	Follow the instructions for use
	Keep dry
	Store at relative humidity levels between 10 % and 93 % RH
	Store between -20 °C and +60 °C
	The device must not be disposed of with household waste
	Direct current

	Type BF Equipment
	Manufacturer
	Batch code (YYMMXXX, Year/Month / Identification number)
	Caution! Read the instruction manual.
	Manufacturing date

EN

Annex

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.

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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 establishments, including domesticestablishments, and those directly connected to the public low-voltage power supply networkthat supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Annex

Guidance and manufacturer´s declaration – electromagnetic emissions			
The device or system is intended for use in the electromagnetic environments listed below. The customer and/or user of the device or system must ensure that it is used in an electromagnetic environment as described below:			
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 typicalcommercial or hospital environment.

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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	Separation distance / 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	0.12	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

<table>
<tr><td colspan="4">Guidance and manufacturer´s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The device or system is intended for use in the electromagnetic environments listed below. The customer and/or user of the device or system must ensure that it is used in an electromagnetic environment as described below:</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 – test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2"></td><td>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.</td></tr>
<tr><td>Recommended separation distance:</td></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td>d= 1.2 √P</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>d = 1.2 √P
80 MHz to 800 MHz</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2"></td><td>d = 2.3 √P
800 MHz to 2.5 GHz</td></tr>
<tr><td>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 electro-magnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity ofequipment marked with the following symbol:</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, 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.</td></tr>
</table>

Annex

Guidance and manufacturer´s declaration – electromagnetic immunity	
a)	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 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.
b)	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
1)	This equipment needs to be installed and put into service in accordance with the information provided in the user manual;
2)	Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment. (Note: As indicated in Table 6 of IEC 60601-1-2 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m)

The current version of the standards is valid.

EN

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