

**Digital Blood Pressure Monitor
for the upper arm**

Geratherm[®]
med control



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INSTRUCTION MANUAL

GT-5907

CE 0197

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Designated use

This unit uses the non-invasive 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. The cuff circumference is 22 to 30 cm (8.7 to 11.81 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 over 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.
- 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.

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Precautionary measures

- 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" 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.

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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 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.

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.

Is my blood pressure normal?

See the blood pressure classification chart released by the WHO (World Health Organization) on page 39 for evaluation of your blood pressure level.

What about low blood pressure?

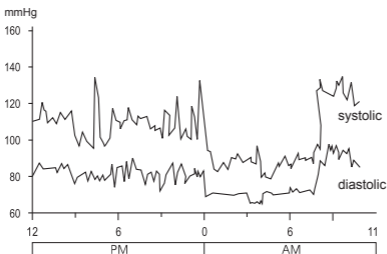
In general, a lower blood pressure reading is better unless causes unpleasant symptoms such as fainting and/or lightheadedness.

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Information you should know before operating the unit

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

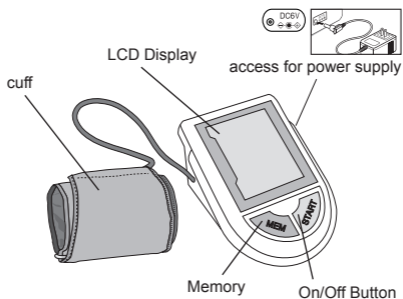
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About the unit

Function description

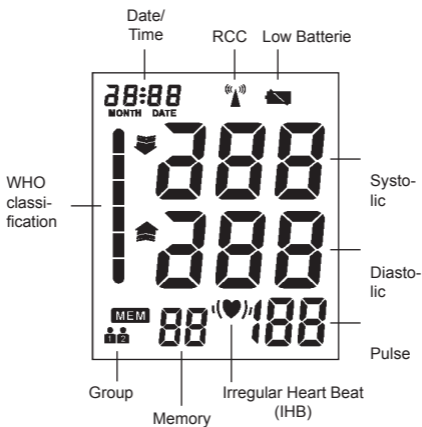
Based on oscillometric method and silicon integrate pressure sensor technology, blood pressure and heart rate can be measured automatically and non-invasively which helps to ease the operation. The Geratherm med control have 2 x 99 memories with date and time display, a big LCD screen and arrhythmia detection. The RCC (radio controlled clock) function can automatically receive the German radio clock signal (DCF77) to adjust the clock accurately. And the colour LED for indicates the class according to WHO of your blood pressure. Also the monitor has the function of averaging the latest three records.

About the unit



The cuff is designed to fit arm sizes between 22 and 30cm (8.7 to 11.81 inches.)

Explanation of displays

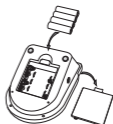


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Preparation for use

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.
4. REMOVE all of the BATTERIES when utilizing an optional AC adapter.



Note:

It is recommended that the same type of alkaline batteries be used to avoid incompatibility. Rechargeable batteries with a voltage of 1.2V are not suitable for this product.



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

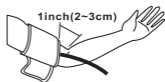
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Attaching the pressure cuff

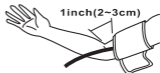
1. Wrap the cuff around the left arm. The arm should be bare.



2. 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.



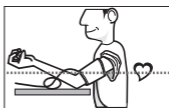
2. Attach the cuff on the right arm as shown in the figure if it is not possible to measure on the left arm.



Preparation for use

Posture during measuring

1. Sit upright and ensure that the cuff 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.



AC adapter (accessory)

Use the device only with a medical approved stabilized AC adapter (6V, DC, 600mA).



Note:


1. No batteries are required during operation using the AC adapter.
2. If AC adapter power is interrupted during measurement, the unit must be reset by disconnecting the AC adapter from the unit.
3. 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 clock and date

1. Clock Mode

Once you install the batteries, with two “beep”, the LCD will display the time and date by turns. At the same time, the machine enters the Radio Controlled Clock Mode with the RCC symbol  twinkling. After the RCC receiving, the machine enters the Clock Mode and the LCD displays the time and date by turns. And the COLOUR CHANGE LED will twinkle with the colour changed in random turn.

2. Radio Controlled Clock(RCC) Receiving

a. Initial receiving:

Once you install the battery, the machine enters the RCC Receiving Mode. The RCC symbol twinkles during the receiving process. If clock data received, the time and date will be adjusted automatically. And then enter the Clock Mode. If no clock data received, the machine enters Clock Mode and keeps the time and date unchanged.

When the machine is in the RCC Mode, you can skip RCC receiving and enter the Clock Mode by pressing “START” button.

b. Forced RCC Receiving

When the machine is in Clock Mode, keep on pressing both the button “START” and “MEM” at the same time for two seconds, you will enter forced RCC mode and the RCC symbol is twinkling. If clock data received, the time and date will be adjusted automatically. And then enter the Clock Mode with two “beep”. If no clock data received, the machine enters Clock Mode with long beep and keeps the time and date unchanged.

You can skip forced RCC Mode by pressing the button “START”. Then the machine enters the Manual Clock Adjusting mode.

c. Periodical receiving

The machine will automatically receive the RCC signal at the time 2:05 and 14:05 every day. You can skip the receiving process by press the button “START” to enter clock mode.

Operations

3. Manual Clock Adjusting

Normally, the time and date can be adjusted by RCC signal automatically. But you also can try manual clock adjusting if no RCC signal or weak signal.

- a. When the machine is in Clock Mode, press the "START" and "MEM" button at the same time (abt. 2 sec.), the machine enters Forced RCC Receiving mode, then press "START" button, the machine enters manual Clock Adjusting Mode.
- b. The number of year will twinkle first. Press "START" button continuously, the numbers of month, day, hour and minute will twinkle in turn. While the number is twinkling, press "MEM" button to increase the corresponding number. Keep on pressing the button "MEM", the number will increase fast.
- c. You can exit the Clock Adjusting Mode by pressing button "START" when the number of minute is twinkling, then enter the Clock Mode.
- d. When you change the batteries, the clock will be reset. You can readjust clock or let the monitor modifying the clock by RCC automatically.

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Measuring blood pressure

- a. After your body is in a comfortable position, press the "START" button. After a long "beep", BPM will verify itself with LCD display all automatically, and the COLOUR CHANGE LED will lighten with 3 colours by turn (picture 1).



pic. 1

- b. Then the LCD twinkle the current group sign and show the total of memories in this group. Now you can modify the current group number by pressing the "START" button, and confirm the current group by pressing the "MEM" button.

Operations

- c. Once you choose the group, and if it already has memory, LCD will show the latest result with the LED indicator (picture 2).

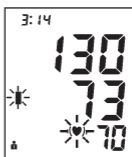
If machine does not have memory before, the LCD will show six "0".



pic. 2

- d. One second later, LCD shows a single "0". While the "down arrow" does not twinkle until the air pressure is stable, and then it begins to measure automatically.
- e. Then the monitor begins to pressurize automatically. During the measurement, the current pressure will display on the LCD, and the bars will automatically rise up or fall down with the current pressure in the cuff. The heart sign will glimmer with the heartbeat during the pressure are falling down.

- f. After measurement, the result of systolic, diastolic and pulse rate will all display on LCD. And irregular heartbeat symbol and blood pressure classification indicator will twinkle (picture 3). The result will be automatically memorized by itself. And the COLOUR CHANGE LED will also indicate the blood pressure classification.



pic. 3

- g. During the measurement, you can turn off the monitor by press the "START" button.
- h. Pressing "START" button after measuring, machine will be turn off, or it will be automatically shut down after 1 minutes of none use.

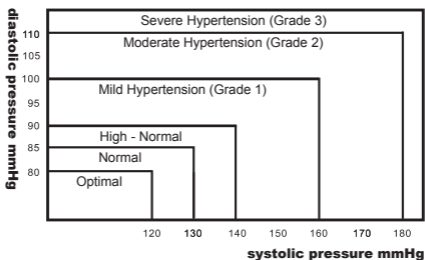


Note:

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.

Operations

WHO classification of blood pressure for adults



Blood pressure classification	Systolic BP mm HG	Diastolic BP mm Hg	Color indicator
Optimal	< 120	< 80	Green
Normal	120 – 129	80 – 84	Green
High – Normal	130 – 139	85 – 89	Yellow
Stage 1 Hypertension	140 – 159	90 – 99	Red
Stage 2 Hypertension	160 – 179	100 – 109	Red
Stage 3 Hypertension	\geq 180	\geq 110	Red



Please note that other risk factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration and may affect these figures. Consult with your physician for accurate assessment.

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Operations

Recalling memories

- a. Under the clock-displaying mode, press button "MEM" will enter the mode of recalling memories. LCD will show how many results it has in the current group. Now you can modify the current group number by pressing the "START" button, and confirm the current group by pressing the "MEM" button.
- b. When the group is selected, the average of last three records will be displayed. If machine does not have memory before, the LCD will show four "0".
- c. After that the latest result will be displayed, which is 01 for memory number. The time which you measured will also be displayed. Continuously press the "MEM" button, previously memories will show by turns.
- d. All memories have the WHO classification and the COLOUR CHANGE LED will also indicate the blood pressure classification.
- e. If it has no memory (or all memories have been deleted), then LCD will show "0" for systolic, diastolic, and show "00" for the numbers of memory, heart rate.
- f. Press "MEM" button again after the last memory, the machine will power off. Under the memory-displaying mode, it will be automatically power off after 1 minute of none use. Or you can press "START" button to shut down the machine.





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Erasing memories

When it displays one memory (no matter which memory), holding on pressing "MEM" button for three seconds, all memories will be deleted with three "beep". LCD will show the "--" before you release the button, then it comes to the mode without memory.





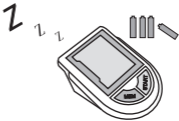

Care and maintenance

<p>Do not drop the unit. It is not shock-proof.</p>	
<p>Do not modify or disassemble the unit or the arm cuff.</p>	
<p>Do not twist the arm cuff.</p>	
<p>Use a cloth moistened with water or neutral detergent to clean the body of the unit and then wipe it dry.</p>	

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Care and maintenance

<p>Avoid thinning agents, benzene, and other harsh cleaners.</p>	
<p>Keep the unit in a suitable place. Avoid high temperatures, direct sunlight, high humidity level, and dust.</p>	
<p>GB</p> <p>Remove the batteries if the unit will not be used for a long time.</p>	
<p>Do not press the START button if the cuff has not been properly wrapped around the arm.</p>	

It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinic). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.

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.



Error messages

Abnormality	Reason	Checkout
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again
	Body posture was not correct during testing	Review the "BODY POSTURE DURING MEASUREMENT" sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this blood pressure monitor.
LCD shows low battery symbol 	Batteries low	Change the batteries

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Error messages

LCD shows "Er 0"	Pressure system is unstable before measurement.	Don't move and try again.
LCD shows "Er 1"	Systolic pressure detect fail	
LCD shows "Er 2"	Diastolic pressure detect fail	
LCD shows "Er 3"	Pneumatic system blocked or cuff is too tight during inflation	Place the cuff correctly and try again
LCD shows "Er 4"	Pneumatic system leakage or cuff is too loose during inflation	
LCD shows "Er 5"	Inflation above 300 mm Hg	Measure again after 5 minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows "Er 6"	Pressure is over 15 mm Hg for longer than 3 min. At the start of measurement the pressure reading must be below 15 mm Hg.	
LCD shows "Er 7"	EEPROM accessing error	
LCD shows "Er 8"	Device parameter check error	
LCD shows "Er A"	Span error	
BPM no response when you press button. BPM hang	Incorrect operation or strong electromagnetic interference	Take out batteries for five minutes, and then reinstall all batteries.

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Technical alarm:

Should the recorded blood pressure (systolic or diastolic) lies outside the limits specified in "Specifications" the technical alarm will appear on the display indicating either "HI" or "Lo". You should seek medical assistance and check the accuracy of your procedure.

The limit values for the technical alarm are factory set and cannot be adjusted or deactivated.

The signal shown on the display will disappear automatically after about 8 seconds.

Specifications

Model No.	GT-5907
Display System	Liquid Crystal Display
Measuring Method	oscillometric method, automatic air inflation and measurement
Power Source	4 alkaline "AA" type batteries (1.5V) or AC adapter (6V, DC, 600mA)
Measuring Range	blood pressure measuring range: 0 to 300 mmHg Heart pulse rate range: 40 to 180 pulse beats /min
Accuracy	±3mmHg (blood pressure) ±5% (pulse rate)
Memory	2 x 99 times with time and date displaying
Low Battery Indicator	yes
Auto Power-Off	after 1 minute
Battery Life	Approx.200 measurements
IP Classification	IPX0 (no protection)
Cuff size	22 to 30 cm (8.7 to 11.81 inches)
Operating Environment	+5°C to +40°C; RH ≤ 90 %
Storage Environment	-20°C to +55°C; RH ≤ 90 %
Dimensions	160mm x 115mm x 69mm
Weight	364 g (monitor) +90 g (batteries)

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

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 CE 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 sphygmomanometers

Symbol index

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	Follow instructions for use		Type BF Equipment
	Keep dry		Batch code (mm/yyyy; month/year)
	Store at a max. relative humidity of 90 %		Serial number
	Store between -20 °C and +55 °C		Manufacturer
	The device must not be disposed of with household waste.		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.

Annex


Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environments listed below, and should only be used 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 domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer's declaration – electromagnetic emissions			
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
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.

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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 disturbances are 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 according to frequency of transmitter / m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
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	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ 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. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
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.		

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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.



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