Digital Blood Pressure Monitor for the Upper Arm

Geratherm®
active control+

EN

INSTRUCTIONS FOR USE

GT-1115

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 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 with an arm diameter of 22 ~ 42 cm / 8.7 - 16.5 inches.

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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, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

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

⚠ Precautions

- This manual and the product are not substitutes for consulting a physician. 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 physician.
- Please ask your physician before using the device on pregnant women, patients with implanted, electrical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your physician prior to using the unit if you suffer from any of these illnesses.
- 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.
- Do not take any therapeutic measures on the basis of a self-measurement. Never alter the dose of a medicine prescribed by a physician. Consult your physician if you have any questions about your blood pressure.
- Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than arm or for functions other than obtaining a blood pressure measurement.
- If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the "START" button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure
- >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
- Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.

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- Do not wrap the cuff around an arm to which medical devices are attached, as this could lead to temporary functional failure of the medical devices being used.
- Avoid any kinks in the air hose during use, as this could lead to a continuous increase in the cuff pressure and cause injury to the patient.
- This unit is not suitable for continuous monitoring during medical emergencies or surgery. This unit cannot be used simultaneously with high-frequency surgical devices.
- This unit is not intended for the transportation of patients outside medical establishments.
- In order to avoid inaccurate measurements, do not expose the blood pressure monitor to strong electromagnetic fields.
- The material of the cuff has been tested and meets 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.
- Do not use the cuff on damaged skin.
- Do not use the device in the case of known allergies to polyester or synthetic materials.
- In order to avoid accidental strangulation, keep the device away from children and do not lay the tube around the neck.
- Do not connect the air hose to any other medical devices, as this can lead to high pressure or conduct air into intravascular systems, which may lead to injury.
- Before using the unit for the first time, ensure that there is no visible damage to the unit.
- Please operate the unit under the environmental conditions described in the instructions. Otherwise, the performance and service life of the blood pressure monitor will be adversely affected.
- 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.
- Dispose of the unit, accessories and components in accordance with local regulations.

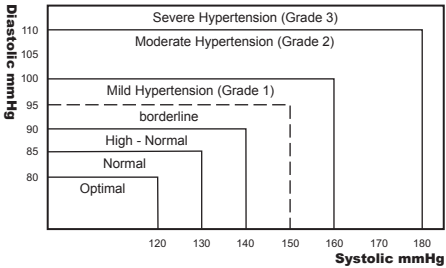
- In the event of malfunction, do not attempt to repair the unit yourself. Only permit repairs to be carried out by authorised technicians.
- In the event of unexpected error messages, please contact your dealer.
- For cleaning, please use a soft cloth and a solvent-free cleaning agent.

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.

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.



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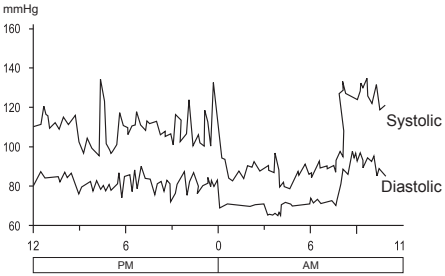
Classification of blood pressure monitor	Systolic mmHg	Diastolic mmHg	Colour indicator
Optimal	< 120	< 80	green
Normal	120 - 129	80 - 84	green
High - Normal	130 - 139	85 - 89	green
Grade 1 Hypertension	140 - 159	90 - 99	yellow
Grade 2 Hypertension	160 - 179	100 - 109	orange
Grade 3 Hypertension	>= 180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

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.

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.



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

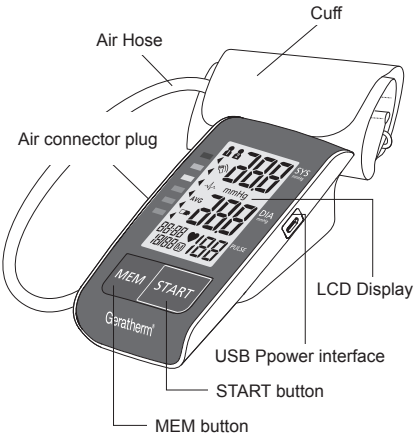
- Bathing
- Drinking alcohol
- Moving
- Meals
- Thoughts
- Conversation
- Exercise
- Stress
- Temperature change
- Smoking etc.

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If major pulse irregularities occur, the arrhythmia icon appears on the display along with the blood pressure readings.

CAUTION

The appearance of the arrhythmia icon indicates that a pulse irregularity consistent with an irregular heart-beat was detected during measurement. Usually this is **NOT** a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Information about the Device



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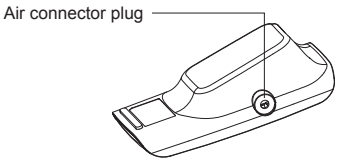

Content:

1. Blood pressure monitor (GT-1115)
2. Cuff (Type BF applied part) 22 cm - 42 cm
3. User manual
4. USB cable (5 V = 1 A)
5. Storage bag

The cuff is designed to fit arm sizes between 22 and 42 cm (8.7 to 16.5 inches).

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 result in inaccurate.
M	Memory	The displayed measurement values is from the memory.
AVG	Average value	The average value of the latest 3 blood pressure measurement results
Lo	Low battery	Battery is low and need to be charged
	Arrhythmia	Irregular heartbeat detection
	WHO classifi-cation	WHO evaluation of the measured values
88:88 18/88	Current date and time	Month/Day, Hour/Minute
	Heartbeat	Heartbeat detection during the measurement
1	User 1	Start measurement and save the measuring results for User 1
2	User 2	Start measurement and save the measuring results for User 2

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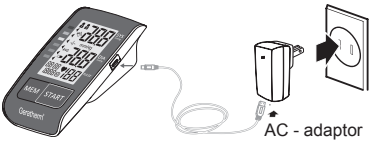
Power Supply and Charge Power

1. The battery of Geratherm active control+ is a built-in rechargeable lithium-ion battery with an electrical charge of 1000 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



AC - adaptor

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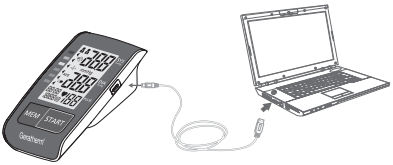
Method 2



Note: Optional Adapter
(Please use any authorized 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 displays on the LCD

Notes

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

If the LCD display " Lo " appears, this means that the battery charge is too low. The blood pressure monitor will switch off automatically and you must recharge it immediately.

During recharging, the LCD display flashes and shows the following symbols:

If it is not charged at all, the following symbols appear on the LCD display during charging:

If charge level 1 has been reached, the following symbols appear on the LCD display during charging:

If charge level 2 has been reached, the following symbol appears on the LCD display during charging:

If charge level 3 has been reached, the following symbol appears on the LCD display during charging:

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Caution

- The battery of Geratherm active control+ is a built-in rechargeable lithium-ion battery. Please do not try to disassemble or force open the blood pressure monitor yourself or permit unauthorised maintenance personnel to do so.
- 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 use the blood pressure monitor during the recharging process. When the unit is fully charged, please pull out the plug in good time.
- 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.

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)

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.

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

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

6. After the [MINUTE] is set, the LCD will display all the settings you have done and then turn off.

Select User

1. When the monitor is off, press and hold "START" button to enter user setting mode. The user ID will blink.

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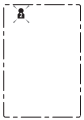
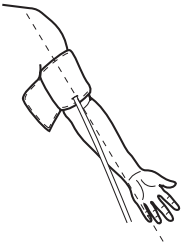
2. Then press "MEM" button to select the user ID between User 1 and User 2.



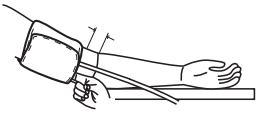
3. After selecting the suitable user ID, press "START" button to confirm. Then the LCD will turn off.

Attaching the Pressure Cuff

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



2. Fasten the cuff in place. Do not pull too hard on the cuff and do not wrap it too tightly. The edge of the cuff should be approximately 2.5 centimetres from the crook of the arm.



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

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Posture during measurement

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.

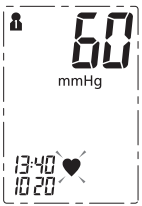
Measuring blood pressure

1. When the monitor is off, press the “START” button to turn on the monitor, the measurement will be completed automatically.

LCD display

0 – value is displayed

Inflating and measuring



Display and save the measurement results

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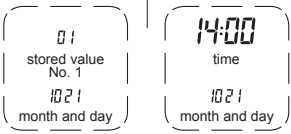
2. As soon as measurement is completed, the blood pressure and pulse readings appear on the display. Press the “START” button to switch the unit off. Otherwise, the unit will switch off automatically after one minute.

Both User 1 and User 2 have 60 memory slots.

Retrieving stored readings

1. In order to retrieve the latest readings, press the “MEM” button and release it. The display will show the average value (AVG) of the last three readings. (Note: If fewer than three readings are available, the latest reading is shown)

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



⚠ 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.

3. In order to retrieve the readings of another user, select that user in advance. See section on “Selecting a user”.
   To retrieve the stored readings, press the “MEM” button and release it.

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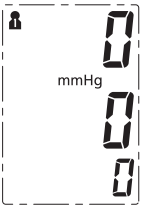
4. Press “START” button to power off, otherwise it will turn off within 1 minute.

Deleting readings

1. Press and hold the “MEM” button for about 3 seconds when the unit is already in memory mode.
   The user and “dEL ALL” (delete all) appears on the display.

2. Press the “MEM” button to confirm the deletion process. “dEL dOnE” (deletion done) appears on the display.

3. To check whether the deletion process was successful, press the“MEM” button. “0” should appear on the display.



Note:
To leave deletion mode without deleting readings, press the “START” button.

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Do not drop the unit.	
Do not modify or disassemble the unit or the arm 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.	

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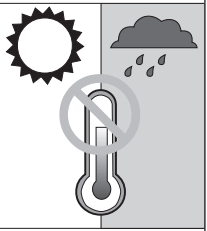
Avoid thinner, benzine, and other harsh cleaners.	
Keep the unit in a suitable place. Avoid high temperature, direct sunlight, high moisture, and dust.	
Do not press the “START” button if the cuff has not been properly wrapped around the arm.	

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Problem	Display symbol	Cause	Solution
No power	Nothing appears on the display	Battery charge too low	Charge battery
Low battery power	 indicator	Battery charge low	Charge battery
No display	No display when buttons pressed	Unit is not activated	Press and hold down “MEM“ button to activate the unit
Error messages	E 3	The cuff is not properly fastened or pressure in the cuff is too high	Rest for a short time, re-fasten the cuff and measure the blood pressure again.
	E10 or E11	The unit has detected movement or pulse rate is too low.	Rest for a short time and retake the measurement.
	E20	No pulse signal is detected	Loosen clothing around the arm and measure again.
	E21	The measuring process was not successful.	Rest for a short time and retake the measurement.
	EExx	A calibration error has occurred	Start the measuring process again. If this problem re-occurs, contact your dealer.
		Measured values are outside the measurement range	Relax for a moment. Re-fasten the cuff and measure again. If the problem re-occurs, consult your physician.

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Specifications

Model-No.	GT-1115
Model-No.	3,7 V 1000 mAH built-in rechargeable lithium-ion battery
Display mode	Digital LCD Display V.A. 44 mm x 64 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0 mmHg ~ 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 to 106 kPa
Storage and transportation condition	-20 °C bis +60 °C Relative humidity: 10 % RH to 93 % RH
Cuff size	22 cm ~ 42 cm
Net Weight	approx. 550 g excluding cuff
External dimensions	approx. 131 mm x 78 mm x 42 mm
Attachment	USB cable, user manual, storage bag

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Degree of protection	IP20
Device classification	Battery mode: with built-in lithium-ion rechargeable battery

Subject to changes in the interests of technical progress

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
Labelling	EN 980 symbols for the labelling of medical devices
Instructions	EN 1041 Medical equipment manufac-turers 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: Require- ments and test methods for non-automated measurement type (ISO 81060-1) EN 1060-3 +A2 Non-invasive blood pressure monitor - Part 3: Supplementary requirements for electromechanical blood pressure measuring system

Quality standard

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

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	Follow the instructions for use
	Keep dry
	Store at relative humidity levels between 10 % and 93 % R.H.
	Store between -20 °C und +60 °C
	The device must not be disposed of with household waste
	Direct current
	Type BF Equipment
	Manufacturer
	Batch code (YYMMXXX; month/ year/identification number)
	Caution! Read the user manual
	Manufacture date

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:

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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:		
Emission test	Compatibility	Notes concerning the EM environment
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	

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	3 A/m	The power frequency magnetic field should be measured at the intended place of installation in order to ensure that it is low enough.

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	0.12	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 higher frequency range should be used.		
NOTE 2:	These guidelines may not be applicable in all situations. Electromagnetic propagation is influenced by absorption and reflection from buildings, objects and people.		

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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.[b] Interference may occur in the vicinity ofequipment 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.
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.

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