Accurate Mini BPM User Manual
Model: AMB -001

Introduction

Thank you for choosing the Accurate Mini Non-invasive Blood Pressure Monitor.

This blood pressure monitor uses the pulse transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and heart rate of adults in a non-invasive manner.

Accurate Meditech is not responsible for any personal or property damage caused by the use of this device that is not incompliance with those authorized by these instructions.

This manual is only applicable to Accurate Mini Non-invasive Blood Pressure Monitor (hereinafter referred to as "Device")

Intend Use

Accurate Mini Non-Invasive blood pressure monitor is a small, lightweight, wrist-worn device intended for measuring and displaying blood pressure (Systolic and Diastolic) and pulse rate.

The Accurate Mini Non-invasive BPM is intended for use by adult patients in hospitals, clinics, long-term care, and home use. The measurement results are stored locally in the device.

Indication for Use

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients of ages 20 -70 with wrist circumference from 13.5 cm to 21.5 cm and BMI<40.
The Accurate Mini Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use. The measurement results are stored locally in the device.
The Accurate Mini Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from Near InfraRed Spectroscopy (NIRS) Optic sensor.

Safety Announcements

Please read the Important Safety Information in this instruction manual before using this monitor.
Please follow this instruction manual thoroughly for your safety.
Please keep for future reference. For specific information about your own blood pressure, CONSULT WITH YOUR PHYSICIAN.

⚠ Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves. DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
⚠ DO NOT use this monitor on an injured wrist or a wrist under medical treatment.
⚠ DO NOT apply the wrist cuff on your wrist while on an intravenous drip or blood transfusion.
⚠ DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
⚠ DO NOT use this monitor in oxygen rich environments or near flammable gas.
⚠ Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia；renal disease or on vasoactive drugs. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
⚠ NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
⚠ This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.
⚠ Battery Handling and Usage : Keep batteries out of the reach of infants, toddlers or children.
⚠ DO NOT use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.
⚠ Do not use while charging.

⚠ Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

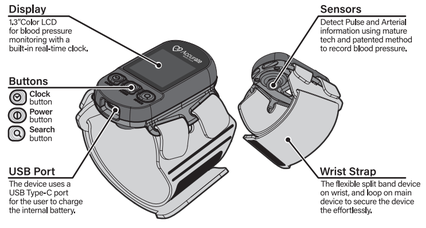
⚠ Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders.
⚠ DO NOT use this monitor for any purpose other than measuring blood pressure.
⚠ DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
⚠ DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
⚠ DO NOT use this monitor in a moving vehicle such as in a car.
⚠ DO NOT drop or subject this monitor to strong shocks or vibrations.
⚠ DO NOT use this monitor in places with high or low humidity or high or low temperatures. Refer to “Specifications”.
⚠ DO NOT use this monitor after the durable period has ended. Refer to “Specifications”.
⚠ After storing the monitor at the highest or lowest storage temperature, Accurate Meditech Inc. recommends waiting approximately 2 hours for the monitor to warm up or cool down before using it in the specified temperature range. For more information on operating and storage/transport temperatures, please refer to “Specifications”.

Note

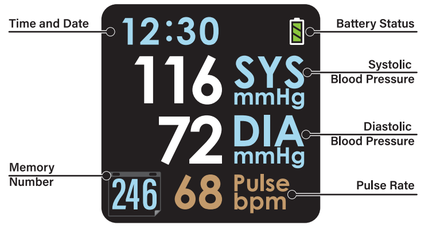
Important tips on the operation and use

- For patients with arrhythmia, premature heartbeats, atrial fibrillation, arteriosclerosis, hypoperfusion, diabetes, nephropathy, a weak pulse, pregnant patients, or patients with significant fluctuations in their heart rate, it may be difficult to measure the blood pressure exactly. Please consult a qualified physician to interpret your blood pressure measurements.
- The device is a non-Invasive Wrist Blood Pressure Monitor and clinically investigated according to the requirements of ISO 81060-2:2018 (4.1 Clinical investigation method of the a.1: a non-invasive auscultatory reference sphygmomanometer at the upper arm.)
- If those who are equipped with a heart pacemaker, a stent, and beyond the measurement ranges of the device, the accuracy of the output results will be affected.
- Check the battery power after each use. When the battery is less than 1 cell, you must charge the battery, and ensure sufficient storage of electricity.
- Please stop using the device if there is any indication of malfunction.

Know Your Device



Content	Description
Display	Show graphic user interface and measurement related content
Power button	Press to turn on / off the device. (Auto measurement starts at power on when the Time and Date are set)
Search button	Press to check History Record
Clock button	Press to change or check settings include Time and Date
USB Type-C port	Connect a USB power source to charge the device
Wrist strap	To secure the device on wrist with circumference 13.5 cm to 21.5 cm



Battery Display

Our device contains a lithium battery that can be used multiple times, please use our included USB charging cable to charge it. The information of battery status is shown on the monitor screen. These battery symbols tell you the current battery status.

Symbols	Description
	The Electricity = 100%
	The Electricity ≤ 60%
	The Electricity ≤ 20%
	The Electricity ≤ 5%
	Charging

- When the or symbol appears on the display, it is recommended you charge it.
- When the symbol appears on the display, "Battery Low " will appears on the screen.
- When the battery is charging, the screen will appear

Please refer to “Recharge the Battery” for instruction on how to recharge.

⚠ Caution

When the device is recharging it will not function. Wait for the recharging sequence to be completed and then proceed to use the device.

Before Taking a Measurement

To help ensure an accurate reading, follow these directions:

1. Avoid bathing, drinking alcohol or caffeine, smoking, exercising, and eating for 30 minutes before taking a measurement.
2. Rest for at least 5 minutes before taking the measurement.
3. Stress raises blood pressure. Avoid taking measurements during stressful times.
4. Measurements should be taken in a quiet place.
5. Remove tight-fitting clothing from your arm.
6. Keep a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a time. Try to measure your blood pressure at the same time each day for consistency.

Using the Device

Date and time set procedure

1. To adjust the date and time, press the “CLOCK” button.
2. The display will show a blinking number representing the YEAR. Change the YEAR by pressing the “SEARCH” button. Each press will increase the number by one in a cycling manner. Press the “CLOCK” button to confirm the entry. The screen will then show a blinking number representing the MONTH.
3. Change the MONTH, DAY, HOUR, and MINUTE as described in Step 2 above, using the “SEARCH” button to change the numbers and the “CLOCK” button to confirm the entries.

▲Repeat the process to set MONTH, DAY, HOUR, and MINUTE.

Applying the Wrist Strap

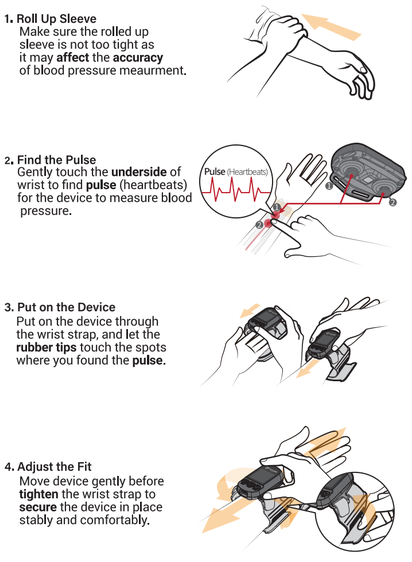
Note

- The blood pressure can differ between the right wrist and the left wrist, and the measured blood pressure values can be different. Accurate recommends always use the same wrist for measurement. If the values between both wrists differ substantially, please check with your physician as to which wrist to use for your measurements.

⚠ Caution

- Remove tight-fitting, thick clothing and any accessories from your wrist while taking measurements.

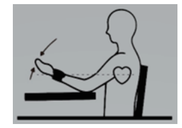
How to Wear



How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated, at a comfortable room temperature.

- Sit in a chair with your legs uncrossed and your feet flat on the floor.
- Sit upright with your back straight.
  Sit with your back and arm being supported.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.
- Your device must be approximately the same height as your heart.



Note

- When the device is about at the same height as the heart, the device will prompt the light function. If the device is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.
- If you are unable to make any seat or table adjustments, please make sure that the height of the device is positioned as close to heart-level as possible and ignore the prompt lights.

Taking a Measurement

⚠ Caution

- DO NOT use this monitor with another medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and /or cause an inaccurate reading.
- Remain still and do not talk while taking measurements.

1. Press the “POWER” button.
2. Check the positioning indicator.
   Your device has a built-in positioning sensor that is used as an aid in determining if the device is at the correct height. When your device is at the correct position relative to your heart, blue indicator light will be displayed on the right side of the screen. Due to difference in individual size and physique, this feature may not be helpful in all cases, and you may wish to disable this feature. If you feel the position of the wrist according to positioning indicator's guidance does NOT match your heart level and follow your judgement.
3. Duration of Measurement is about 25 seconds
4. When the measurement is completed, systolic pressure, diastolic pressure, and pulse will be shown simultaneously on the screen. The measurement is then automatically stored in memory.

Note

- This monitor automatically turns off approximately 1 minute after the last operation. You may also press the “POWER” button to turn the unit off.
- To interrupt measurement, you may press the “POWER” button to turn the unit off.
- This spot-checking device provides only one blood pressure measurement during a single recording session.

Viewing the Readings Stored in Memory

Your device automatically stores up to 480 readings. If the maximum number of 480 data records has been reached, the oldest data record will be deleted and the new data record will be saved in the first slot.

Press the “SEARCH” button.

246 The identifying number of current saved User

Press the “SEARCH” and “CLOCK” buttons. repeatedly to scroll through the previous readings stored in the memory.

Recharge the Battery

⚠ Caution

When the device is recharging it will not function. Wait for the recharging sequence to be completed and then proceed to use the device.

Steps

- Find the included USB cable in the box.
  Insert the Type C-USB (smaller end) into the device.
  Insert the USB-A (larger end) into a power adaptor.
- If an extension cord is used, please make sure it is plugged in securely.
- The display will show once power input detected.
- Unplug the cable from the device once is shown.
- The device will show current time for 3 seconds then turn off.

Troubleshooting

If any abnormality arises during use, please check the following points

Display Problem	Possible Cause	Solution
E001	Piezo sensor 1(upper sensor) failure	Contact your local distributor representative.
E002	Piezo sensor 2 (lower sensor) failure	
E005	Optical sensor 1(upper sensor) failure	
E007	G sensor failure	
E008	Battery fault	
E009	Data acquire failure	
E010	Signal noise too large	
E011	Measurement failure	Re-apply the Wrist strap, then take another measurement.
W001	Detect movement	
W002	The Wrist strap is too tight	
W003	The signal is saturation	Repeat measurement. Remain still and do not talk during measurement. Refer to “Taking a Measurement”.
Battery Low	Low Battery Alarm	Please charging the Battery.
No power. Nothing appears on the display of the monitor.	The battery is completely depleted.	Contact your local distributor representative.
	Broken Button	
	Broken Battery	
Any other problems occur.	Press the “POWER” button to turn the device off, then press it again to take a measurement. If the problem persists, contact a local distributor representative.	

Maintenance

To protect your device damage, From damage follow the directions below:

- Changes or modifications not approved by the manufacturer will void the user warranty.

⚠ Caution

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

Storage

Keep your monitor in the storage case when not in use.

- Store your monitor in a clean, safe location.
- Do not submerge the device or any of the components in water.
- Do not operate the device in extreme temperatures, humidity, or direct sunshine.
- Do not violently shake the unit or drop it on the floor.

Cleaning

- Do not use an alcohol-based cleaning solution or solvent to clean the device.
- Use a soft dry cloth or a soft cloth moistened with neutral soap to clean your monitor and Wrist strap, and then wipe them with a dry cloth.
- Do not wash or immerse your device and Wrist strap in water.
- Turn off the “POWER” button before cleaning the device.

Battery

- This device has a built in battery that cannot be removed.
- Do not charge the battery using cables or devices as it may cause damage to the batter.
- Do not expose the battery to fire as it is an explosion hazard.
- Do not use the battery to supply power for other electronic devices.
  Destruction of the battery should comply with local laws and regulations.
- For maximum battery life only recharge it in accordance with these instructions. As a minimum it should be recharged once a month for late least 1 hour. Charging time should never exceed 12 hours.
- In case of failure during the warranty period contact the retailer.

Specfications

Product description	Automatic Wrist Blood Pressure Monitor
Model	AMB-001
Display	LCD digital display (TFT)
Pressure range	0 to 299 mmHg
Blood pressure measurement range	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg
Pulse measurement range	40 to 250 beats/min.
Accuracy	Mean difference ≤ ±5 mmHg Standard deviation ≤±8 mmHg Pulse: ±5% of display reading
Measurement method	Pulse transit time with the hemodynamic method
IP classification	IP 22
Rating	DC 5V 1A max
Power source	250 mAh
Battery life	150 measurements with full charge battery
Durable period	3 years
Operation conditions	5 ℃ to 40 ℃ / 10 to 95% RH / 70.0 kPa ~ 106.0 kPa
Storge/Transport conditions	-20℃ to 55℃ / 10 to 95% RH / 70.0 kPa ~ 106.0 kPa
Weight	Approximately 50g
Dimensions	69mm x 43mm x 23.25mm (NOT including the Wrist strap)
Measurable wrist circumference	13 cm to 21.5 cm
Memory	Stored up to 480 readings
Contents	Device/Type C USB cable/User manual
Protection against electric shock	Internally powered ME equipment
Wrist Strap material	Nylon & Spandex, Polyurethane
Applied part	Type BF

Guidance and Manufacturer's Declaration

- Comply with IEC 60601-1:2012 “Medical electrical equipment -Part 1: General requirements for safety".
- Comply with IEC 60601-1-2:2014 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”.
- Comply with IEC 60601-1-11:2015 “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".
- Comply with IEC 80601-2-30:2018" Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers".

Symbol Description	
	Type BF (Body Floating)
	Follow the Instruction
IP22	Water Proof Level
	Manufacturer
	Production Date
	Expiration Date
LOT	Lot Number
REF	Product Number
	Waste Electrical and Electronic Device (WEEE) Directive
	DO NOT use if the packaging is damaged
MR	DO NOT use the device in an MR environment.
	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

Manufacturer	Accurate Meditech Inc. 12, Ln. 609, Sec. 5, Chongxin Rd., Rm.10, 8F., Sanchong Dist., New Taipei City 241406, Taiwan www.accurate-meditech.com +886-2-2999-1596

Important information regarding Electro Magnetic Compatibility (EMC)

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

For conformity with the requirements for EMC (Electro Magnetic Compatibility), with the aim to prevent unsafe situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

The medical device's functions/performance and a description of what the operator can expect if the functions/performance are lost or degraded due to EM disturbances. For 60601-4-2, these are the functions/performance needed to demonstrate the medical device performs as intended, and for all other 60601 standards this is Basic Safety and Essential Performance.

Medical devices manufactured by Accurate Meditech Inc. conform to this EN60601-1-2 standard for both immunity and emissions. Reference to the applicable standard can be found in the instruction manual of the product.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Accurate Meditech Inc., may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- During use (or measurement), portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by Accurate Meditech Inc. Otherwise, degradation of the performance of the device could result.
- Refer to further guidance below for individual products regarding the EMC environment in which the device should be used.

Correct Disposal of This Product (WEEE)

- In order to avoid the pollution and infecting others, other device and environment, the device should be cleaned before the disposal of device and according to local regulation (regulations on disposal of electronic and electrical components and device) it can be disposed. If there is no related regulation, please dispose of it in accordance with the rules of the disposal of waste in the local hospital.
- Do not throw away battery randomly and knock it down, and then contact with the local supplier. This product must be recycled and processed in accordance with local law.
- Please do not treat obsolete electrical or electronic device as unclassified municipal waste. Collected separately, the device can be safely, properly reused, treated, and recycled.

FCC Caution

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates uses and can radiate radio frequency energy and, if not installed and used following the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures :

- Reorient or relocate the receiving antenna.
  Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.
- This device complies with FCC radiation exposure limits set forth for an uncontrolled environment and can be used without any restrictions.

Manufacturer's declaration-electromagnetic emissions

The AMB-001 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the AMB-001 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home healthcare environment)
RF emissions CISPR 11	Group 1	The AMB-001 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AMB-001 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity

The AMB-001 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the AMB-001 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s) ± 0.5 kV, ±1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ±1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 30 cycles Voltage interruptions: 0 % U_T; 300 cycles	Mains power quality should be that of a typical home healthcare environment. If the user of the AMB-001 requires continued operation during power mains interruptions, it is recommended that the AMB-001 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The AMB-001 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The AMB-001 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the AMB-001 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the AMB-001** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800MHz to 2,7 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). Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distance between portable and mobile RF communications equipment and the AMB-001

The AMB-001 is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the AMB-001 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AMB-001 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	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 2,7 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 meters (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.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The AMB-001 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the AMB-001 should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
1 720 1 845 1 970	1,700 – 1,990	GSM 1800; CDMA 1900, GSM 1900; DECT; LTE Band 1, 3, 4, 25;	Pulse modulation b) 217 Hz	2	0,3	28	28
2 450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The AMB-001 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the AMB-001 should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home healthcare)
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.