Electronic Sphygmomanometer
User's Manual

Guangdong Biolight Meditech Co., Ltd.

Product Information

- Product Model: WBP100/WBP201/WBP202
- Product Name: Electronic Sphygmomanometer
- Manufacturer Name: Guangdong Biolight Meditech Co.,Ltd.
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- Service life：5 years

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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Statement

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The contents contained in this manual are subject to amendments without notification.

Manufacturer's Responsibility

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument:

- All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.
- The storage condition, operation condition and electrical status of the instrument conform to the product specification.
- The instrument is used in accordance with the user’s manual.

About this manual

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Illustrations are for reference only. They may be not in conformity with your products.

Signs in this manual：

Warning: Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

Caution: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Note: Provides application tips or other useful information to ensure that you get the most from your product.

Contents

1、 Intended Use

The device is intended to measure blood pressure and pulse rate of adult. The measurement data is available for clinical reference. It can store, manage the measure data, and transmit the measuring result via wireless signal.

It is intended to be used in clinic, general ward, physical examination department and at home.

Caution:

- **The patient is the operator when the device is used at home or in public areas;**
- **The device is intended for use only by clinical professionals and in continual attendance when it's used in hospital.**

2、 Application

The device is reusable and intended for measuring human blood pressure and pulse rate.

- Application population

  Adult.

- Measurement site

  Place a bare arm through the cuff and position the cuff 1-2cm above the elbow joint.

3、 Safety Information

Warning:

- **Don't take measurement immediately after smoking, drinking alcohol, coffee and black tea, or within an hour after a meal;**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external equipments operated in the vicinity of the device comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation;**
- **The device is designed for adults and should never be used on infants,**

pregnant, pre-eclampic patients or people with serious arrhythmia. Consult your physician before use on children;

- **Don't use the electronic sphygmomanometer in the environment containing inflammable anesthetic gas;**
- **Consult your physician for any of the following situations:**

a) The application of the cuff over a wound or inflamed area;

b) The application of the cuff on any limb with intravascular access or therapy, or an arterio-venous (A-V) shunt;

c) The application of the cuff on the side of a mastectomy;

d) Simultaneous use with other medical monitoring equipment on the same limb;

- **The device cannot be used together with high-frequency electrotomes and defibrillators;**
- **Please do not use the device while it is charging;**
- **Please do not measure immediately after an intense movement or a bath;**
- **This product might not meet its performance specifications if stored or used outside the specified temperature, humidity and altitude ranges;**
- **Please do not share the cuff with any infectious person to avoid cross-infection;**
- **Battery replacement should only be performed by personnel who have been confirmed qualified by the manufacturer. To do otherwise will void your warranty and possible damage your unit;**
- **Any form of modification to this device is forbidden.**

Caution：

- **Make sure that the appropriate cuff size is used;**
- **Cuff is replaceable and its replacement can only be conducted by manufacturer.**
- **We recommend the users to use the original manufactured cuff and adapter. If not, it might cause measurement error or product failure;**
- **If the adapter is abnormal, please change the adapter;**
- **Too high cuff pressure or too long charging time may make users feel uncomfortable, and cause ischemia and neuropathy. Please turn off the device in time and take off the cuff;**
- **The device and adapter should be considered as a medical system. The power**

adapter must be provided or designated by manufacturer (see optional item list). If use another power adapter, it should be verified, otherwise electric shock may occur and cause patient death;

- **The effective wireless transmission distance is 5m in a barrier-free environment. If more than this distance, the product might not work. Please use this product within effective wireless transmission distance;**
- **The charging cable should be put beyond children to avoid the danger of strangulation;**
- **If children or pets beat, throw or tramp on the device, it might affect the performance of the device. Please put the device beyond children and pets;**
- **The main unit, cable, battery and cuff must be disposed according to the local regulations at the end of their usage.**

Caution:

- **Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment;**
- **This equipment 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 equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with 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 equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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 equipment and receiver.

  -- Connect the equipment 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.

Note：

- **Doctor should make diagnosis on clinical manifestation and symptoms, only with using the device as subsidiary.**
- **Blood pressure can be affected by the position of the cuff, measuring posture and your physiologic condition;**
- **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;**
- **The device complies with the standard of IEC 80601-2-30;**
- **If the determined blood pressure (systolic or diastolic) is outside the rated range specified in part specifications, the device will immediately display an error code on screen. In this case, consult a physician or ensure that proper measurement procedures are followed;**
- **Patients can use all functions of the device safely according to this user's manual;**
- **Any questions about setting, using or maintaining the device, please contact with manufacturer;**
- **If unexpected operation or events appear in use process, please report to the manufacturer;**
- **When measuring, the following conditions may lead to the measured results have differences:**

a) Talking ; b)After defecate or urinate;

c) After the bath; d) Different measurement site or environment;

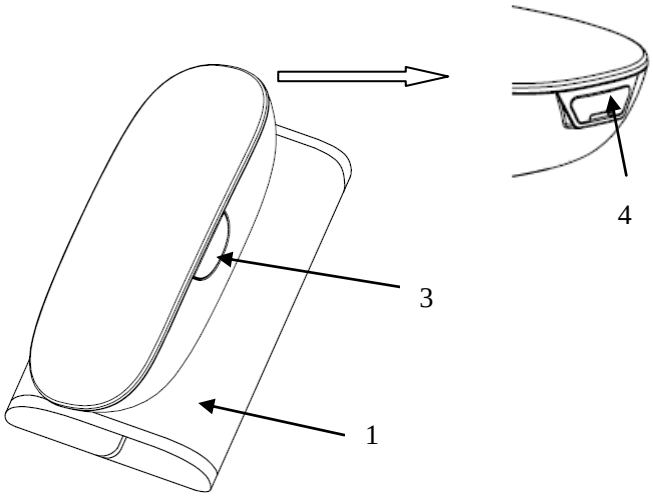
e) After smoking; f) After drinking alcohol, coffee and black tea;

g) After the movement; h) Room temperature changes suddenly

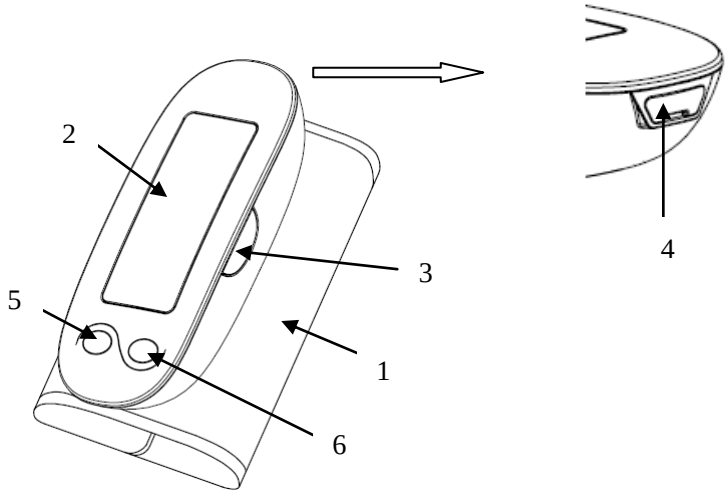
i) Within an hour after a meal; j) Mood be agitated when caused by tension, uneasy.

4、 Appearance

- **WBP100：**



◆ **WBP201/WBP202：**



1、 Cuff

2、 Display screen

Display systolic blood pressure, diastolic blood pressure, pulse rate and so on.

3、 Power button；Start/Stop button

— Long press (press and hold it more than 2s) this button to turn off the device;

— When the power is off, short press (press and hold it less than 2s) this button to turn on the device. Otherwise, short press it to start/stop the NIBP measurement.

4、 Charging cable interface

Connect to the power supply for charging.

5、 Select users button

— In measurement sate: Short press this button to select users;

— In setting state: Short press this button, the time value would increase one.

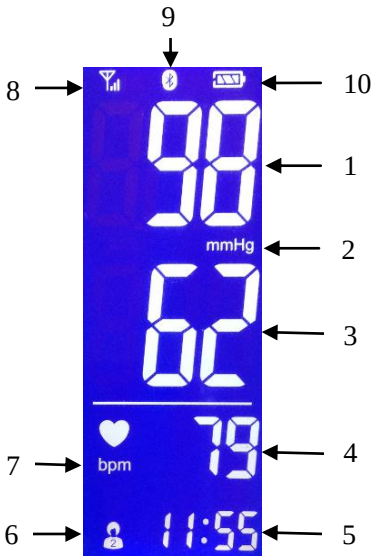
6、 Historical data review button

— Not in setting state: Short press this button to review historical data. Long press it to enter setting mode.

— In setting state: Short press this button to switch the setting items. Long press it to save the setting and quit setting mode.

5、 Display

1. Systolic blood pressure;
2. Blood pressure unit;
3. Diastolic blood pressure;
4. Pulse rate;
5. Time;
6. Users name;
7. Pulse rate unit;
8. Signal quality;
9. Bluetooth state;
10. Battery state.



When measuring error, such as transducer failure, loosely wrapped cuff, screen displays the wrong code. The definition of the error code and the possible reason are as follows:

Error code	Definition	Possible Reason
E02	Self-test failed	Transducer or other hardware failure.
E06	Loose cuff	a. Cuff is completely unwrapped; b. No cuff attached;
E07	Air leak	Air leak in pneumatics, hose, or cuff.
E08	Air pressure error	Unit cannot maintain stable cuff pressure, e.g. kinked.
E09	Weak signal	a. Very weak patient signal due to a loosely wrapped cuff; b. Extremely weak pulse from patient.

Error code	Definition	Possible Reason
E10	Range exceeded	Measurement range exceeds module specification of 255 mmHg maximum.
E11	Excessive motion	a. Too many retries due to interference of motion artifact; b. Signal is too noisy during step-down to detect pressure pulse, e.g. subject has severe tremor; c. Irregular pulse rate, e.g. arrhythmia.
E12	Overpressure sensed	Cuff pressure exceeds software safety limit, 295 mmHg in Adult mode. Could be due to rapid squeezing or bumping of cuff.
E13	Signal saturated	Large motion artifact that saturates the BP amplifier's amplitude handling capability.
E14	Air system leak	Module report Air system leakage Failure while in the Air System Leakage Test mode.
E15	System failure	Abnormal events.
E19	Time out	Measurement took more than 120 seconds in adult.

6、 Setting

You can set the time and date of this product. The setting method is as follows:

Press the historical data review button "  "and hold it for 3 seconds to enter the year setting interface. The third number of the year starts to flash. When you press the select users button "  " once, the third number increase 1 (It means the year increases ten years).

After you finish setting the third number of year, press the historical data review button "  " to enter the setting interface of the fourth number. The fourth number of the year starts to flash. When you press the select users button "  " once, the fourth number increase 1 (It means the year increases 1 year).

Set month, day, hour, and minute in the same way.

After you finish setting time and date, press the historical data review button "  " to enter the setting interface of blood pressure units (The default unit is mmHg). When a flashing mmHg appears on the screen, it means the blood pressure unit is mmHg. Press the select users button "  ", mmHg would disappear and kPa would appear. Press the button "  " again, kPa would disappear and mmHg would appear. So repeatedly, you can switch between the two units. Press the historical data review button "  " and hold it for 3 seconds to end the setting after you finish setting unit.

7、 Historical data review function

This device can record the blood pressure, pulse rate and time automatically to facilitate the management of blood pressure. Press the historical data review button "  ", the latest measurement result would be displayed on the screen. Press the button "  " again, the second latest measurement result would be displayed. And so on, you can review all the historical data.

8、 Download And Install The Software

1、Software download methods：

Users who use the IOS system device can log in iphone App Store, enter "Biolight" and search for the software of "BP tracker" in the searching results.

Users who use the Android system device can log in the wearcare official website: *http://www.wearcare.cn* for download.

2、Download the software of "BP tracker", click installation button for free installation.

9、 Using Steps

◆ **Preparation before measurement**

1、Keep your body and mood calm, take off the thicker clothes such as coat, sweater, Etc. When measuring, bare upper arm or wear thinner shirt.

2、Long press the power button to turn on the device. (Users, who use APP software, need to open the Bluetooth of the device and terminal, open the APP software, and connect with the device)

Caution：

■ **When a call comes in during the measurement, the measurement will be terminated. It is recommended that IOS device be set in Airplane mode during measurement to avoid strong magnetism interference.**

◆ **Using Steps**

(1) Apply the cuff

- Loosen the calibre of the curly cuff slightly. Place a bare arm through the cuff directly according to the instruction icon " ⬅ UP", " DOWN ➡". Position the cuff 1-2cm above the elbow joint and ensure the mark "Φ" on the cuff shall lie above artery.

- Pull one end of the cuff to the lateral and tighten. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.

Caution:

- **Make sure that the appropriate cuff size is used. Refer to the cuff circumference range in the Specification section of this manual.**

(2) Body posture

Stay still and calm for five minutes before taking a blood pressure measurement.

Be seated with your feet flat on the floor without crossing your legs. Place your hand palm-side up in front of you on a flat surface such as a desk or table. The cuff should be placed at the same level as your heart.

Note:

- **Incorrect measuring posture showed as follows might cause an incorrect measurement:**
  - **a) Bent over（lean forward）;**
  - **b) Sitting cross-legged;**
  - **c) Bend the body because of the low table or sitting on sofa.**

(3) Measuring

- Select users: Press the Select users button to select users, you can select user 1 or user 2;
- Start measuring: Press the power button, then the cuff pressure automatically and the screen shows rising pressure values. Stay still and calm during measurement. Do not move your arm, body and the device.

(4) Display the measurement value

The device exhausts automatically and displays the measurement results. About the display interface of measurement results, please refer to chapter "***5 Display***".

Users, who use the APP software, can read the measurement results on the software interface.

(5) Take off the cuff

(6) Turn off the device

Long press the power button to turn off the device after the measurement.

Note:

- **While measuring blood pressure, the users must stay still and calm without any talk;**
- **The cuff tied on the limb shall be on the same level as the patient's heart so as to avoid the reading error resulting from the hydrostatics effect of the blood flow between the heart and cuff. If the cuff position is higher than heart level, the BP reading will be lower, the measured result shall be added 0.75mmHg (0.1kPa) for each centimeter higher; in case the cuff position is lower than heart level, the BP reading will be higher, the measured result shall be deducted 0.75mmHg (0.1kPa) for each centimeter lower;**
- **If the signal measurement time is more than two minutes and the device doesn't exhaust automatically, please take off the cuff and turn off the device.**

Caution：

- **You can stop the measurement process at any time by pressing "Start/Stop button".**

Warning:

- **Prolonged and frequent NIBP measurements are associated with ischemia and neuropathy in the limb wearing the cuff. Please examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the NIBP measurements.**
- **Too frequent measurements may have influence on the measurement results.**

10、 Maintenance and Cleaning

1、 Clean the traces on the host or display with a dry, soft cloth or tissue;

2、 The most commonly used hospital cleaning agent and non-corrosive detergents can be used for cleaning the device, but please be careful that many types of detergents must be diluted before use; Please use them according to the directions of the manufacturers of the detergents;

3、 The casing of the device should be kept from the contamination of filth and dirt, and it can be wiped with non-velvet soft cloth. When cleaning, do not spill the liquid onto the instrument. Ensure no liquid is allowed to enter the inside of the device;

4、 It is recommended that if the cuff is used, for example, in hospital or a clinic, it be disinfected twice a week, Wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75%-90%). Then air dry the cuff.

5、 Please do not clean or wet cuff. Please do not soak the device in liquid;

6、 Please store the host and the cuff in a cool and dry place;

7、 Do not drop the device or subject it to strong impact.

Caution：

- **Avoid using alcohol-based, amido or acetone-based detergents.**
- **Please put the main unit and its accessories beyond infants and young**

children to avoid dangerous accident.

- **Under normal circumstances, it is unnecessary for the device to have special maintenance, and cautions must be exercised on the following points during the use of the device.**

  ——Please use the device in the environment according to the requirements of the performance criteria;

  ——Avoid exposure or direct sunlight;

  ——Avoid excessive radioactive infrared rays or ultraviolet rays;

  ——Avoid contacts with organic solutions, dusts or corrosive gases.

- **No device component needs to be maintained by the user. Electrical schematic diagram and component list are only provided to repair station or personnel which have been confirmed qualified by the manufacturer;**
- **Check the device regularly please. If you doubt the measurement result is not accurate, please contact the manufacturer.**

11、 Accessory and Specifications

11.1 Optional item

Items	Mode
Power adapter (optional)	LXCP12-05(Output DC5V,1.0A)

11.2 Technical Specifications

Production model	WBP100、WBP201、WBP202
Size	130 mm(L) x 55 mm(W) x 30 mm(H)
Weight	＜350g
Measure specifications	
Measurement way	Automatic oscillometry
Measurement range **Systolic:** **Diastolic:**	 30 mmHg～255 mmHg（4.0kPa～34.0kPa）; 10 mmHg～220 mmHg（1.3kPa～29.3kPa）;
Pressure accuracy **Static:** **Clinic:**	 ±3 mmHg Average error: ±5 mmHg, standard deviation: ≤8 mmHg
PR range and accuracy	40 bpm～240 bpm，±5% or ±3bpm, whichever is the greater
Blood pressure unit	"mmHg" or "kPa"

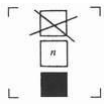
Software overpressure protection		295±5 mmHg
Measurement time		Normally, it is 20s to 45s (depending on HR and moving interference typically) Maximal measurement time: 120s
LED indicating lamp		
WBP 100	**Bluetooth indicating lamp**	1 (Blue) Not connected: The lamp flashes blue; Connected: The lamp lights blue without flashing; (When the device is power off, the lamp is off.)
	Charging indicating lamp	1 (Orange) Light up: When the battery is being charged or when the DC power supply is connected; Off: When the battery is fully charged.
WBP 201 **WBP 202**	**Bluetooth state indicating**	Not connected: The indicating flashes; Connected: The indicating lights without flashing;
	Battery state indicating	The electric quantity of battery is divided into four ranks to display the current electricity. Being Charged : The indicating flashes; Not being charged or fully charged: The indicating lights without flashing.
Bluetooth		
Bluetooth version		Bluetooth 4.0 with low power consumption.
Transmission frequency		2440 MHz
Wireless transmission distance		＜5m
App software platform		
IOS system		iPhone 4s、iPhone5、iPhone5s、iPhone 6、iPad3+、iPad mini
Android (4.3+) system		Mobile phone, Palmtop computer
Battery		
Type		Rechargeable lithium ion battery
Rated voltage		3.7 VDC
Capability		600 mAh
Operating time		≥24 h
Charge time		≤2 h
Cuff		

Large cuff	32 cm～42cm（Optional）
Medium cuff	22 cm～32cm（With）
Small cuff	17 cm～22cm（Optional）
Adapter	
Input	100～240V, 50/60Hz 0.3Amax
Output	DC 5V, 1A
Environment specifications	
Temperature	Operating: 5℃～+40℃; Transportation and storage: -20℃～+55℃.
Humidity	Operating: 25%～95%（non condensing）; Transportation and storage: 25%～95% (non condensing).
Atmospheric pressure	Operating: 700hPa～1060hPa; Transportation and storage: 500hPa～1060hPa.

12、 Troubleshooting

Symptom	Possible Reason	Solution
No response or cannot turn on the device	1. The battery power might be at shortage or no electricity; 1、 The device itself might be damaged.	1、 Please charge the device; 2、 Contact customer service.
The data cannot be display properly or display reads an abnormal result	1. The cuff position was not correct or it was not properly tightened; 2. Speaking, moving arm or body, being angry, excited or nervous during test.	1. Review the cuff application instructions and retest; 2. Retest when calm; avoid speaking or movement during the test.
Cannot make connection between device and receiver	1. Bluetooth does not be open on receiver; 2. The version of Android in the receiver device isn't 4.3 or 4.3+; 3. The version of Bluetooth is not 4.0; 4. Out of connection range.	1. Open Bluetooth; 2. Upgrade the Android system to version 4.3 or 4.3+; 3. Use the receiver device with Bluetooth 4.0; 4. Close to receiver.

13、 Equipment Symbols

Symbol	Symbol Note
	Type BF applied part, without defibrillation protected.
	Refer to this user's manual.
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC
LOT	Batch code
SN	Serial number
IP22	Enclosure degree of ingress protection.
	Federal Communications Commission
IPX0	**Power adapter** Degree of protection against ingress of liquid
	Fragile. Show transport package contents fragile, so handling should be handled with care.
	Upward. It shows the correct position of the transport package is upright.
	Guard against wet. Show packages afraid be wet.
	Stacking layer limit. Same packing maximum stacking layers, N represents the number of layers limit. (N is 6).

14、 Blood pressure general knowledge

14.1 Definition of blood pressure

Blood pressure is the pressure on the vessel wall side. When the heart is contracting, the blood pressure is the highest at this time and is called the systolic pressure. When the heart is relaxing, the blood pressure is the lowest at this time and is called the diastolic blood pressure.

14.2 Classification of blood pressure

The World Health Organization (WHO) has created the following blood pressure classify table for assessing high blood pressure (without regard age or gender). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) also need to be considered. Consult with your physician for accurate assessment.

Scope	**Systolic blood pressure (SYS) kPa/mmHg**	**Diastolic blood pressure (DIA) kPa/mmHg**	**Corresponding measure**
Hypotension	≤13.3/100	≤8.0/60	Ask physician for measuring.
Normal blood pressure	13.3/100～18.7/140	8.0/60～12.0/90	Self measure.
Mild Hypertension	18.7/140～21.3/160	12.0/90～13.3/100	Consult physician.
Moderate Hypertension	21.3/160～24.0/180	13.3/100～14.7/110	Consult physician.
Severe Hypertension	≥24.0/180	≥14.7/110	Danger! Please see the doctor as soon as possible.

Note：This table is not intended to provide a basis for any type of emergency condition or diagnosis. This table only depicts different classification of blood pressure. Consult your physician for proper interpretation of blood pressure results.

Appendix A Guidance and Manufacturer's Declaration of EMC

Note:

- **This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.**
- **Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.**

Caution:

- **This unit has been thoroughly tested and inspected to assure proper performance and operation.**
- **This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.**

Guidance and manufacture's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device use 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 emission 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 manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
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 floor 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	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) 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.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 Vrms

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1{,}2\sqrt{P}$
$d = 1{,}2\sqrt{P}$ 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 meters (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:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">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 re-orienting or relocating the device.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between

portable and mobile RF communications equipment and the device .

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
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.

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.