材质：内页普通80g书写纸，

成品尺寸:100×140mm

420mm

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Eiffestrasse 80, 20537 Hamburg, Germany.
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Version Number:1.0

CE 0123

Fully Automatic Upper Arm

Blood Pressure Monitor

Model Number: BA31/BA31T

USER'S MANUAL

CONTENTS

1.Introduction and Intended Use

This device is a fully automatic digital blood pressure measuring device,it is intended to measure systolic and diastolic blood pressure as well as the pulse by wrapping around the upper arm with cuff circumference ranging from 22cm to 42cm .
The device is used for adult that age is more than 12 years old ,and the intended populations are the patients with hypertension or need blood pressure monitoring. The device can be used in medical facilities or at home,and only for indoor use.

Contraindication: The device is not used for patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids.

Before using, please read this instruction manual carefully and then keep it in a safe place.

1.1 Remember…

- Only a health-care professional is qualified to interpret blood pressure measurements.
- This device is NOT intended to replace regular medical checkups.
- Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should YOU alter the dosages of any drugs prirately unless you have the permission of physician.
- This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.
- In cases of irregular heartbeat , measurements made with this instrument should only be evaluated after consultation with a physician.
- The products, including accessories, shall be processed in accordance with local regulations after reaching the life cycle.

1.2 Warnings and Precautions ⚠

Warning:	The use of other accessories other than those specified or provided by the equipment manufacturer may cause electromagnetic radiation to increase or decrease electromagnetic immunity resulting in operational failure
Warning:	This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.
Warning:	Use only the qualified AC adapter that complies to the IEC60601-1 requirement to ensure the safety.
Warning:	Do not use the AC adapter if the unit or the power cord is damaged.Turn off the power and unplug the power cord immediately.
Warning:	The user must check that the equipment functions safely and see that it is in proper working condition before being used.
Warning:	The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
Warning:	If the patient is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by patient. The routine clean and changing batteries can be performed by the patient.
Warning:	This device can not be used together with hf surgical equipment.
Warning:	Use of power adapters 1.Adapter: input 100-240V, 50/60hz output DC 5V 1A 2.Do not be prone to water leakage, high temperature, moisture, direct sunlight and more or more corrosive gas environment. And Do not use this product in the above environment.
Warning:	Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
Warning:	Don't place the cuff over wound part.
Warning:	Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.
Caution:	To avoid any possibility of accidental strangulation, keep this device away from children and do not drape tubing around your neck.

Caution:	To avoid damaging the device, keep this unit away from children and pets.
Caution:	The standard material used for the bladder and tubing is latex-free.
Attention:	The device is intended for monitoring,and not for a diagnsis. Unusual values must always be discussed with a physician. Under no circumstances should you alter the dosages of any drugs prescribed by a physician.
Attention:	The device cannot be used to substitute the professional ECG monitor device for monitoring the frequency of heart beat!
Attention:	In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.
Note:	To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications.
Note:	The cuff is defined as the applied part.The user should contact the manufacturer for assistance, if needed, replace, or maintaining the device.
Note:	This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic results.
Note:	Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

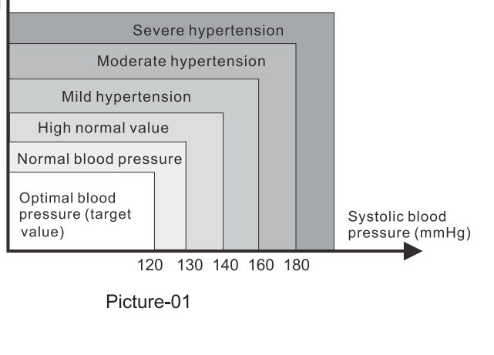
2.Important Information on Blood Pressure and its Measurement

2.1. How does high or low blood pressure arise?

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered.Blood vessel width is controlled by fine muscles in the blood vessel walls.
Your level of arterial blood pressure changes periodically during heart activity: During the "blood ejection" (Systole) the value is highest (systolic blood pressure value). At the end of the heart's "rest period" (Diastole) pressure is lowest (diastolic blood pressure value).

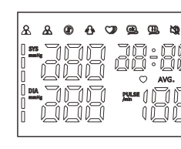
2.2. Which values are normal?

Please refer to the diagram below(Picture-01)



Picture-01

There are six grids in the display of device. Please refer to the picture-01-01. Different grids represent different interval scales of WHO.

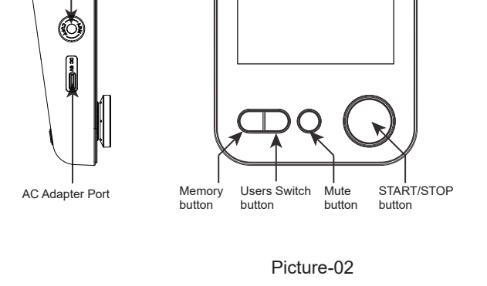


Blood pressure value	WHO grids in device	WHO Classification
DIA<80 & SYS<120	1	Optimal blood pressure
DIA<85 & SYS<130	2	Normal blood pressure
DIA<90 & SYS<140	3	High normal value
DIA<100 & SYS<160	4	Mild hypertension
DIA<110 & SYS<180	5	Moderate hypertension
DIA>=110 or SYS>=180	6	Severe hypertension

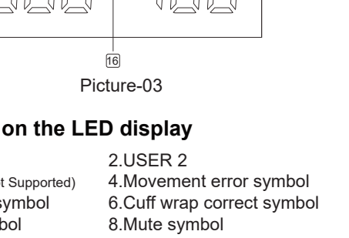
picture-01-01

3. Components of your blood pressure monitor

3.1. Measuring unit



Picture-02



Picture-03

3.2 The symbols on the LED display

1.USER 1
2.USER 2
3.Bluetooth symbol(Not Supported)
4.Movement error symbol
5.Irregular heartbeat symbol
6.Cuff wrap correct symbol
7.Cuff wrap error symbol
8.Mute symbol
9.Low battery symbol
10.Date/Time display
11.AM symbol
12.AM symbol
13.Average value symbol
14.Memory symbol
15.Pulse display / Memory number
16.Heartbeat symbol (Flashes during measurement)
17.WHO function symbol
18.Diastolic blood pressure
19.Systolic blood pressure

3.3 Features of Model

1. Voice function
2. Double users: 2 x 120 sets memory
3. Cuff self-checking function
4. Irregular heartbeat checking
5. Average value function
6. Low battery display
7. WHO function
8. Auto power-off
9. External power adapter support
10. Volume adjustment
11. Date/time display

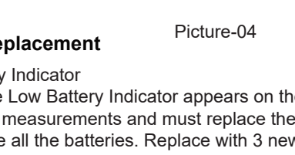
Note: Arm circumference should be measured with a measuring tape in the middle of the relaxed upper arm. Do not force cuff connection into the opening. Make sure the cuff connection is not pushed into the AC adapter port.

4. Using your Monitor for the First Time

4.1 Activating the pre-installed batteries

Battery Installation

Use only 1.5V "AA" alkaline batteries with this device.
1. Press the hook on the bottom of the battery cover and lift the cover off in the direction of the arrow (Picture-04).
2. Install 3 "AA" size batteries and make sure the + (positive) and - (negative) polarities match the polarities of the battery compartment, then close the battery cover.Make sure that the battery cover is securely in position.



Picture-04

Battery replacement

Low Battery Indicator
1.When the Low Battery Indicator appears on the display, You cannot take any further measurements and must replace the batteries.turn the monitor off and remove all the batteries. Replace with 3 new batteries at the same time. Long-life alkaline batteries are recommended.
2.To prevent the damage of monitor from leaked battery fluid, please take out of battery if the monitor unused in a long time(generally more than 3 months). If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
3. Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

4.2. System Settings

Before setting, ensure that all batteries are loaded correctly.

A. Setting the User ID(1 or 2):
With the unit off,Press the ( ) button and then you can set the User ID user by pressing the ( ) button.

B:Setting the voice:
With the unit off,Press the ( ) button and then you can Turn on or off the voice by pressing the ( ) button

C.Setting the Year/Month/Date/ hour system/Time/Volume:
With the unit off,Long press the ( ) button for more than 3s, and then you can start to set.

Setting the Year:
When the year display is flashing, Turn the knob clockwise continuously and it will increase continuously 1 by 1 until 2049, and then return the original year, Turn the knob counterclockwise continuously and it will reduce continuously 1 by 1, once the year set is OK, press the ( ) button to confirm.

Setting Month/Date:
Initial Month/Date is 1/01, when the Month display is flashing, Turn the knob clockwise continuously, the month will increase continuously 1 by 1 ,Turn the knob counterclockwise continuously and it will reduce continuously 1 by 1, press the ( ) button to confirm, and do in the same way to set the date, Press the ( ) button to confirm.

Setting hour system:
Initial hour system is 12 hour ,Turn the knob clockwise or Turn the knob counterclockwise and then you can switch 12 or 24 hour system ,press the ( ) button to confirm.

Setting Time :
When the hour display is flashing, Turn the knob clockwise continuously, the hour will increase continuously 1 by 1, Turn the knob counterclockwise continuously and it wil reduce continuously 1 by 1,press the ( ) button to confirm, and do in the same way to set the minute. Press the ( ) button to confirm.

Setting Volume:
When display with VOL is flashing, Turn the knob clockwise or Turn the knob counterclockwise to switch volume 1,volume 2, volume 3 or oFF. Press the ( ) button to confirm.After the setting is completed, the device switches off automatically and save the setting result.

Note:After the device is powered off, and then reload the battery. The monitor will display the Setting interface.

4.3. Cuff tube connection

Insert the cuff tube into the opening on the left side of the monitor (As shown in picture-05)

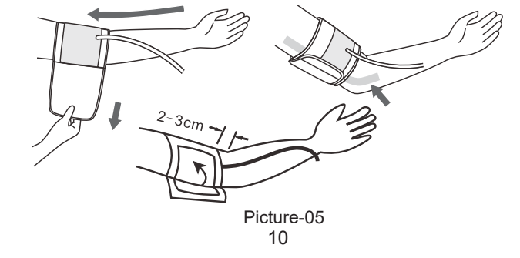
5. Measurement Procedure

5.1. Before measurement:

- Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors influence the measurement result. Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).

5.2. Fitting the Cuff

Please refer to picture-05
a) Wrap the cuff around your upper left arm. The rubber tube should be on the inside of your arm extending downward to your hand. Make certain the cuff lies approximately 2 to 3 cm above the elbow. Important! The Φ on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.
b) To secure the cuff, wrap it around your arm and press the hook and loop closure together.
c) There should be little free space between your arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure your arm circumference if you are not sure of proper fit.
d) Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.



Picture-05

400mm

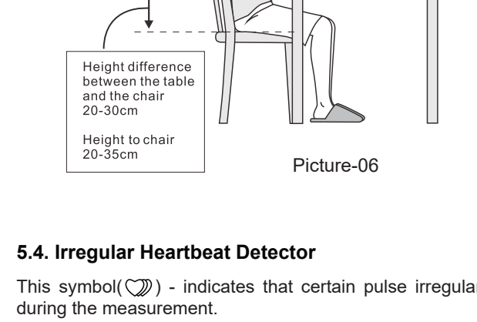
5.3. Measure Procedure

The device is designed to take measurements and store the measurement values in memory for two people using User ID 1 and User ID 2.

Refer to picture-06
1. Sit comfortably in a chair with your feet flat on the floor.
2. Select your User ID (1 or 2).
3. Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned. Make sure arm is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement. After the cuff has been appropriately positioned on the arm and connected to the blood pressure monitor, the measurement can begin:

Operate on the device
a) Press the START/STOP button and then turn the device on ,all symbols appear on the display. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.
NOTE:
1.you can switch the User ID by pressing the ( ) button before the pump begins to inflate the cuff.
2.you can turn off the voice by pressing the ( ) button before the pump begins to inflate the cuff.
b) When the device has detected your pulse, the heart symbol in the display begins to blink.
c) When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.
d) The measurement results are displayed until you turn the device off by pressing the START/STOP button. If no button is pressed for 60 seconds, the device switches off automatically.
e) Cuff self-checking symbol ( )
The cuff correct symbol( ) will be displayed if the cuff position is correct, otherwise the wrong symbol( ) will be displayed. Please check again the cuff if the wrong symbol( ) is displayed.
f) Movement error symbol ( )
The Movement Error Symbol ( ) is displayed if you move your body during the measurement. Please remove the cuff, and wait 2-3 minutes. Reapply the cuff and take another measurement.

NOTE:
Patient Position:
1) Comfortably seated
2) Legs uncrossed
3) Feet flat on the floor
4) Back and arm supported
5) Middle of the CUFF at the level of the right atrium of the heart



Picture-06

5.4. Irregular Heartbeat Detector

This symbol( ) - indicates that certain pulse irregularities were detected during the measurement.
In this case, the result may deviate from your normal basal blood pressure – repeat the measurement.
Information for the physician on frequent appearance of the Irregular Heartbeat Symbol.
This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.
If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

5.5. Error Indicates

The following symbol will appear on the display when measuring abnormal

SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er 1	Sensor abnormal	Check if the pump is working or not. If it is working, then the problem is sensor abnormal. Please send it to the local distributor.
Er 2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	start the measurement again.If the error is still displayed, please send it to local distributor
Er 3	Measurement result is abnormal	Occasionally-measure for one more time/ Always - send it to local distributor
Er 4	Too loose cuff or air leakage	Tie the cuff correctly and make sure the air plug is properly inserted in the unit
Er 5	The air tube is crimped	Correct it and make the measurement again
Er 6	The sensor is sensing great fluctuation in the pressure	Please keep quiet and don't move
Er 7	The pressure that the sensor sensing is over the limit	start the measurement again.If the error is still displayed, please send it to local distributor
Er 8	The demarcation is incorrect or the device has not been demarcated	Please send back to the local distributor

Trouble removal

Problem	Check	Cause and solutions
No power	Check the battery power	Replace new one
	Check the polarity position	Installation for proper placement of the batteries polarities
No inflation	Whether the plug insert	Insert into the air socket tightly
	Whether the plug broken or leak	Change a new cuff
Err and stop working	Whether move the arm when inflate	Keep the body peaceful
	Check if chatting when measured	Keep quite when measure
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Whether the cuff broken	Change a new cuff
⚠ Please contact the distributor if you can't solve the problem, do not disassemble the unit by yourself!		

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor , or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor and its use.

EC REP	Authorized Representative in the European Community
CE 0123	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
SN	Specifies serial number
	Type BF applied part
⎓	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Follow instructions for use

MD	Medical device
↑↑	Put up
	Fragile
☂	Afraid of the rain
☀	Fear of the sun
IP21	The degree of avoid ingress of water or particulate matter into ME equipment
	Handle gently
	Temperature range
No Sterilize requirement	
Not category AP / APG equipment	
Mode of operation: continuous	

5.6. Memory

Each unit stores 120 sets measurements for 2 users,totally 240 sets (User 1 and 2).Measurements for each user are stored separately. Be certain that you are viewing the measurements for the correct user.

A.View the memory
With the unit off, press the ( ) button. The monitor will display User ID and an average value of the last 3 times measurements stored in the unit.
(If measurements are less than 3 sets, directly display the first set)
Turn the knob clockwise, it will display the memory value from the latest to the oldest in turn.
Turn the knob counterclockwise, it will display the memory value from the oldest to the latest in turn.

B. Switch user memory
When viewing the memory, press the ( ) button ,it will switch the User ID, and then display another user memory value .

C.Delete memory:
In average value memory viewing mode,the average value symbol (AVG.) is being displayed, long press the ( ) button for 3 seconds ,then it will delete all measurements for the current user.
In single set memory viewing mode,long press the ( ) button for 3 seconds ,then it will delete only a set measurement being displayed.

Note:
If you decide to delete the all memory, please keep the memory in another way, incase you need it some days later. Take the battery out won' t lead to a memory missing.

5.7. Discontinuing a Measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g the patient feels unwell), the Start/Stop button can be pressed at any time. The device then immediately lowers the cuff pressure automatically.

5.8. Using the AC Adapter

You may also operate this monitor using the AC adapter (output 5V DC1A with Type c connector).
a) Ensure that the AC adapter and cable are not damaged.
b) Plug the adapter cable into the AC adapter port on the left side of the blood pressure monitor.
c) Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed.
Note: No power is taken from the batteries while the AC adapter is connected to the monitor. If electrical power is interrupted,(e.g., by accidental removal of the AC adapter from the outlet) the monitor must be reset by removing the plug from the socket and reinserting the AC adapter connection.

6.Care and Maintenance

Wash hands after each time measurement.
If one device is used by different patients, wash hands before and after each use.
a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
b) The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
c) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds, if necessary, 70% isopropanol can be used. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.
d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
e) Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.
f) Never open the monitor! This invalidates the manufacturer's warranty.
g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

6.1. Accuracy test

Sensitive measuring devices must be checked for accuracy from time to time. We recommend a periodical inspection of your device by an authorized dealer every 1 year. Please turn to local distributor or the manufacturer.

7. Warranty/Service

Your blood pressure monitor is guaranteed for 2 years against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.
Warranty only applies to the main device and its cuff. All other accessories are not covered by warranty.
There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.

8. Certifications

Device standard:
This device is manufactured to meet the European blood pressure monitors:
IEC 80601-2-30 / IEC60601-1-11 / IEC60601-1
Electromagnetic compatibility:
Device fulfills the stipulations of the International standard
IEC60601-1-2

9. Technical Specifications

Model: BA31/BA31T
Weight: 182g (batteries and AC adapter is not included)
Display: 84.4×55.7mm(3.32"×2.19") LED Digital Display
Size: 134(L)×110 (W)×47(H) mm(5.27"×4.33"×1.85")
Packaging list: 1×Main Device, 1×Cuff, 1×Users manual,
Operating Conditions: Temperature: 5℃ to 40℃;Humidity: 15% to 93% RH;
Storage And Shipping Conditions:Temperature: -25℃ to 70℃;
Humidity:≤ 93% RH;
Atmospheric pressure range：70kPa~106kPa
IP classification：IP21

Measuring method: Oscillometric
Pressure sensor: Resistive
Measuring range: DIA: 40-220mmHg; SYS: 60-260mmHg
Pulse: 40 to 199 per minute
Cuff pressure display range:0-295mmHg
Memory: Automatically stores the last 120 measurements for 2 users (total 240)
Measuring resolution: 1 mmHg
Accuracy: Pressure within ± 3 mmHg / pulse ± 5 % of the reading
Power source: a) 3*AA batteries, 4.5 V
b) AC adapter INPUT：100-240VAC 50/60HZ OUTPUT：5V DC 1A
Accessories: Wide range rigid cuff 8.7" – 16.5" (22 - 42 cm)
Users: Adult
Expected service life of the device and accessories: 5 years
Technical alterations reserved!

10. EMC Declaration

1) *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.
2) * 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.
3) * Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4) * Caution: 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 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 ±1 kV for input/output lines	Not applicable	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) ± 2 kV line(s) to earth	Not applicable	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	0 % U_T; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270°, 315° 0 % U_T ; 1 cycle 70 % U_T; 25/30 cycle 0% U_T; 250/300 cycle	Not applicable	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	30 A/m 50/60Hz	30 A/m 50/60Hz	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.

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 the device should assure that it is used in such an environment.

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** $d=0.35\sqrt{p}$ $d=1.2\sqrt{p}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur bands 80% AM at 1kHz	Not applicable	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	80MHz to 800MHz： $d=1.2\sqrt{p}$ 800MHzto 2.7GHz： $d=2.3\sqrt{p}$ 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. ((•)) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

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 other than domestic 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	

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 $d = 1{,}2\sqrt{P}$	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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

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.

Test frequency (MHz)	Band [a)] (MHz)	Service [a)]	Modulation [a)]	Maximum power (w)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse Modulation [b)] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c)] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation [b)] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b)] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3 4,25;UMTS	Pulse Modulation [b)] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b)] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation [b)] 217 Hz	0.2	0.3	9
5500						
5785						

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.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be
calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY
TEST LEVEL in V/m.

FCC Statement:
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.
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 guarant ee 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.
Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environm ent. This transmitter must not be co - located or operating in conjunction with any other antenna or transmitter.