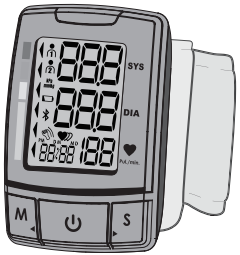
Version:1.0

TRANSTEK

User Manual

Blood Pressure Monitor TMB-1580-BT

Wrist Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1580-BT.
- To use the monitor correctly and safely, please read the manual thoroughly.
- Please keep this manual well in order to reference in future.

Bluetooth SMART

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Zhongshan,528437,Guangdong,China

TRANSTEK

CATALOGUE

♥ General Description

Thank you for selecting TRANSTEK Blood Pressure Monitor (TMB-1580-BT). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Readings taken by the TMB-1580-BT are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- Systolic blood pressure
- Diastolic blood pressure
- Pulse rate
- 60 records per each user

♥ Indications for Use

The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5 cm to 21.5 cm (about 5½"-8½").
It is intended for adult indoor use only.

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
Bluetooth SMART	The Bluetooth Combination Mark		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "MANUFACTURER"		
SN	Symbol for "SERIAL NUMBER"		
⎓	Symbol for "DIRECT CURRENT"		Symbol for "Including RF transmitter"
	Symbol for "MANUFACTURE DATE"		Caution: These notes must be observed to prevent any damage to the device.
	Symbol for "KEEP DRY"		

⚠ CAUTION

This device is intended for adult use only.

This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.

Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.

If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.

If the cuff pressure exceeds 40 kPa (300 mmHg),the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.

To avoid measurement errors, carefully read this manual before using the product.

The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.

The operator shall not touch output of batteries and the patient simultaneously.

Do not use the monitor under the conditions of strong electromagnetic field (e.g. medical RFequipment) that radiates interference signal or electrial fast transient/ burst signal.

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.

Manufacturer will make available on request circuit diagrams, component parts list etc.

This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's wrist and fingers will become anaesthetic, swollen and even purple due to a lack of blood.

Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential alergic reaction or contact injury.

The device doesn't need to be calibrated whith the two years of reliable service.

Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.

When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.

This device is contraindicated for any female subject who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.

Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.

Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.

When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: too frequent and consecutive multiple measurements, the application of the CUFF and its pressurization on any wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; Inflating the cuff on the wrist on the side of a mastectomy.

Do not apply the cuff over a wound, otherwise it can cause further injury.

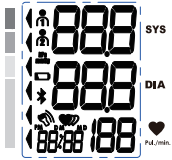
Do not inflate the cuff on the same limb which other monitoring ME EQUIPMENT is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME EQUIPMENT.

Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.

Don't kink the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

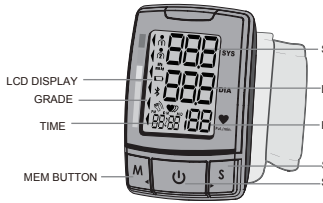
The device has been evaluated clinically using manual cuff/stethoscope auscultation as the reference. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers."

♥ LCD Display Signal

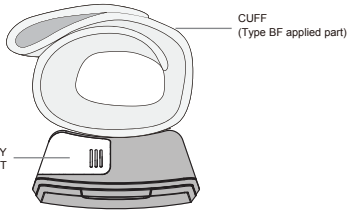


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul./min.	Pulse	Pulse/minute; heartbeats/minute
	Shocking remainding	Shocking will result in inaccurate
+Lo	Low battery	Batteries are low and need to be replaced
kPa	kPa	Measurement unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement unit the blood pressure (1mmHg=0.133kPa)
	Irregular heartbeat	Irregular heartbeat detection
PM YR MO	Current time	Month/Day/Year,Hour/Minute
	Grade	The grade of the blood pressure
	Heartbeat	Heartbeat detection during the measurement
	User 1	Start measurement and save the measuring results for user 1.
	User 2	Start measurement and save the measuring results for user 2.

♥ Monitor Components



Component List:
1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.

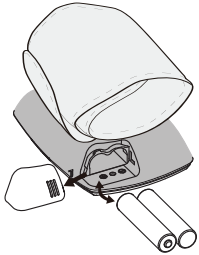


♥ List

1) Blood Pressure Monitor TMB-1580-BT
2) 2×AAA batteries
3) User manual

♥ Installing and Replacing the Batteries

- . Slide off the battery cover.
- . Install the batteries by matching the correct polarity, as shown below. Always use the correct battery type (2 x AAA batteries).
- . Replace the cover.



Replace the batteries whenever the below happen

- The +Lo shows
- The display dims
- The display does not light up

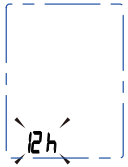
⚠ CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

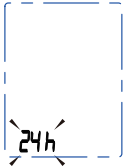
♥ Setting Date, Time and Measurement Unit

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (year :2014—2054,time format:24 H/12 H)

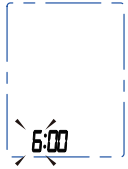
1. When the monitor is off, hold pressing "S" button for about 3 seconds to set the time format.



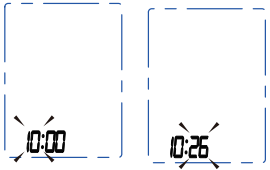
2. Press the "M" button to change the [TIME FORMAT] between 12 hours and 24 hours.



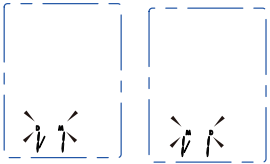
3. When you get the right time format, press "S" button to confirm your selection and it will turn to the next step.



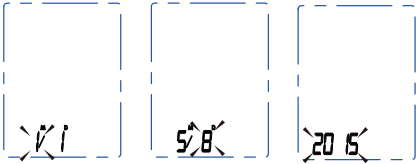
4.Repeat steps 2 and 3 to confirm [HOUR] and [MINUTE].



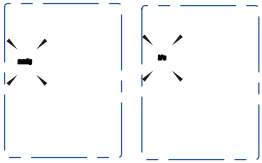
5.Then the monitor diverts to date format setting. Select the date format. Repeat steps 2 and 3 to confirm the date format between DM and MD.



6.Repeat steps 2 and 3 to confirm the [MONTH] , [DAY] and [YEAR].



7.Repeat steps 2 and 3 to confirm the [MEASUREMENT UNIT].



8.After confirming the meausrement unit, the LCD will display “dOnE” and then turn off.

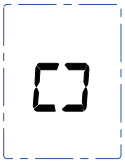
♥ Pair-up the Blood Pressure Monitor with Your Device

1 .Turn on Bluetooth and the app. Make sure both are ON when pair-up is proceeding.

2 .When the monitor is OFF, press and hold START/STOP button about 3 seconds to start pair-up. The symbol  and the symbol will be shown on the LCD alternatively, indicating pair-up is proceeding.

3. Then please select the user ID you want to connect with your smartphone on the app to continute the pair-up.

If SUCCEED, symbol will be shown on the LCD.



If FAIL, symbol will be shown on the LCD.

4 .The monitor will shut off automatically after Pair-up process is complete.

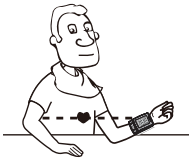
Bluetooth Module No.:	AW2540MV1
RF Frequency Range:	2402 MHz to 2480 MHz
Output Power Range:	-1 dBm
Supply Voltage:	2 V to 3.6V
Transmitting Distance:	10 meters

♥ Tie the Cuff

1. Remove all accessories (watch, bracelet, etc) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1-1.5cm.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.

6. Sit comfortably with your tested wrist resting on a flat surface.
7. Patients with Hypertension:
The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and wrist supported.

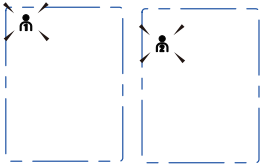
- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- The patient must relax as much as possible and do not talk during the measurement procedure.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as directed by a physician.



♥ Select the User ID

Before you start the measurement, please select the desired user ID first.

1. When the blood pressure monitor is off, press and hold the MEM button until the user ID blinks. Then press “M” button to change the user ID between user 1 and user 2. Press “S” button to confirm your selection.

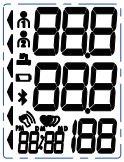


2. After confirming the user ID, the LCD will turn off. Then you can start your measurement now.

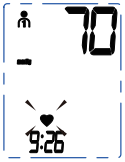
♥ Start the Measurement

1.When the monitor is off, press “START/STOP” button to turn on the monitor, and it will finish the whole measurement. (Take User 1 for example.)

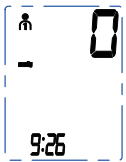
LCD display



Inflating and measuring.



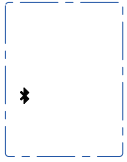
Adjust to zero.



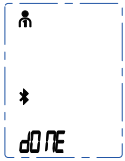
Display and save the result.

2. This device will proceed to data transmission after measurement. The Bluetooth symbol blinks on the LCD indicates data is transmitting.

If the data transmission fails, ᛒ lights all the time.



If the data transmission succeeds, the LCD will display “User ID+ ᛒ +dONE”.



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

Tips: Maximum 60 records are both for User 1 and User 2.

♥ Recall the Records

1. When the monitor is off, press “M” button to show the average value of the latest three measurement records. (Take User 1 for example.)

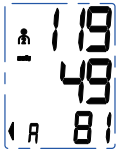
2. Press “M” button or “S” button to get the record you want.

The date and time will display alternately.

The corresponding time is 9:10.

The corresponding date is May 11th.

3. If you want to check the other user’s measurement records, please press “START/STOP” button to turn off the blood pressure monitor. Then press and hold “M” button to enter the selecting user mode, press “M” again to change the user, when the desired user ID blinks, press “S” button to confirm. Then press “M” button to check the records of the selected user.



⚠CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

♥ Delete the Records

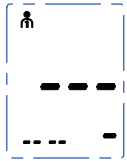
If you did not get the correct measurement, you can delete all results by following steps below . (Take User 1 for example.)

1. In the memory mode, hold pressing “M” button for 3 seconds, the flash display “User ID+ dEL All” will show.

2.Press “S” to confirm deleting , the LCD displays “ dEL dOnE” and the monitor will turn off.

Note: To exit out of delete mode without deleting any records, press START/STOP button before pressing “S” to confirm any delete commands.

3.If there is no record. the right display will show.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

Wait at least 1 hour
after dinner or drinking

Immediate measurement
after tea, coffee, smoking

Wait at least 20 minutes
after taking a bath

When talking or moving your fingers

In a very cold environment

When you want to discharge urine

♥ Maintenance

In order to get the best performance, please follow the instructions below.

Put in a dry place and avoid the sunshine

Avoid touching water,
clean it with a dry cloth in case.

Avoid intense shaking
and collisions

Avoid dusty and unstable-
temperature environment

Using wet cloths to remove dirt

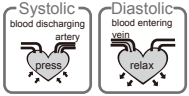
Avoid washing the cuff

⚠ CAUTION

- If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of TRANSTEK. Don't open or repair the device by yourself.
- Please report to TRANSTEK if any unexpected operation or events occur.

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, the highest pressure in the cycle is known as systolic pressure. When the heart relaxes between heartbeats, the lowest blood pressure is diastolic pressure.



♥ What is the standard blood pressure classification?

The chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

AHA Home Guideline for Upper Limit of Normal BP

SYS	135 mm Hg
DIA	85 mm Hg

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140-159	or	90-99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110

⚠ CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15,the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.

⚠ CAUTION

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

♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.

♥ Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:

If the cuff is tied properly.

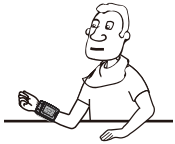
If the cuff is too tight or too loose.

If the cuff is tied on the wrist.

If you feel anxious.

Taking 2-3 deep breaths before beginning will be better for measuring.

Advice: Relax yourself for 4-5 minutes until you calm down.



♥ Is the result the same if measuring on the right wrist?

It is ok for both wrists, but there will be some different results for different people. We suggest you measure the same wrist every time.

This section includes a list of error messages and frequently asked questions for problems you may encounter with your wrist blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	+Lo Show on the display	Batteries are low.	Replace with new batteries
Error massage	E 1 shows	Data communication is failed.	Check if the Bluetooth function of the smartphone is on or it is during the range of distance
	Err 1 shows	The cuff is too loose.	Refasten the cuff and then measure again.
	Err 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	Err 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.

Power supply	Battery powered mode: 2*AAA batteries (3V DC)
Display mode	Digital LCD V.A.35mm×46mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kPa - 40kPa (0mmHg~300mmHg) Measurement pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg) pulse value: (40-199) beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kPa(3mmHg) pulse value:±5%
Normal working condition	Temperature:5℃ to 40℃ Relative humidity: ≤85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃ to 60℃ Relative humidity: 10%RH to 93%RH Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of the wrist	About 13.5cm-21.5cm
Net Weight	Approx.120g(Excluding the dry cells)
External dimensions	Approx.64mmx90mmx57mm (Exclude the cuff)
Attachment	2*AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IPX0
Software version	V01
Device classification	Internally Powered ME Equipment

WARNING: No modification of this equipment is allowed.

♥ Contact Information

For more information about our products, please visit www.transtek.cn.you can get customer service, usual problems and customer download, transtek will serve you anytime.

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd.
Company: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China

♥ FCC Statement

FCC ID: OU9TMB1580-B

Label 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.

FCC Statement
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.

To assure continued compliance, any changes or modifications not expressly approved by the
party responsible for compliance could void the user's authority to operate this equipment.

Radiation Exposure Statement
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled
environment and it also complies with Part 15 of FCC RF Rules.

CAUTION:
To comply with the limits of the Class B digital device, pursuant to Part 15 of the FCC Rules, this device is comply with Class B limits. All peripherals must be shielded and grounded. Operation with non-certified peripherals or non-shielded cables may results in interference to radio or reception.

MODIFICATION:
Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

♥ Complied Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1: 2005+A1：2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements and Clinical investigation	IEC 80601-2-30:2009 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ANSI/AAMI SP10:2002/A2: 2008 Manual, electronic, or automated sphygmomanometers
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes
Usability	IEC 62366 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007) IEC 60601-1-6 Medical electrical equipment - Part 1 -6 : General requirements for basic safety and essential performance - collateral standard : Usability

♥ EMC Guidance

1) This equipment needs to be installed and put into service in accordance with the information provided in the user manual;

2) Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d=3,3m away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d=3, 3m at an IMMUNITY LEVEL of 3V/m)