version:1.0

TRANSTEK

TRANSTEK

User Manual

Blood Pressure Monitor TMB-1591

Arm Type

- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1591.
- 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

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

CATALOGUE

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK arm type blood pressure monitor (TMB-1591). 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-1591 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:

- 68mm*90mm Digital LCD display with White backlight
- Maximum 99 records
- Measuring during inflation technology

♥ Indications for Use

The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm(about 8¾″-16½″).
It is intended for adult indoor use only.

♥ Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

♥ 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 followlocal guidelines.”
	Symbol for “MANUFACTURER”	⎓	Symbol for “DIRECT CURRENT”
	For indoor use only		Symbol for “Class II Equipment”
F1	T1A/250V Φ3.6*10CCC		Caution: These notes must be observed to prevent any damage to the device.
	WARNING:These warning notes must be observed to preventany injury to the user.	SN	Symbol for “SERIAL NUMBER”
IP22	The ingress protection: the device could protected against solid foreign objects of 12.5mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°		
	Symbol for “KEEP DRY”		

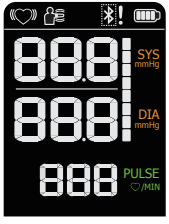
WARNING

1. The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
2. The device is not suitable for use on pregnant women, patients with implanted, electrocical devices, patients with pre-elcampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses
3. Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
4. Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fata.
5. Do not dispose of batteries in fire. Batteries may explode or leak.

⚠ CAUTION

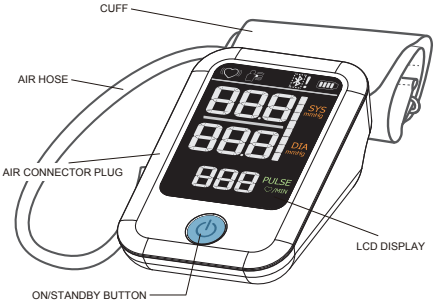
This device is intended only for adult use in homes.
This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than arm or for functions other than obtaining a blood pressure measurement.
If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure >300mmHg or constant pressure >15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis. Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
Do not wrap the cuff on the same arm which other monitoring ME EQUIPMENT is applied simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME EQUIPMENT.
Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
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.
This unit is not suitable for continuous monitoring during medical emergencies or operations.
This device cannot be used with HF surgical equipment at the same time.
This device is not intended for patient transports outside a healthcare facility.
To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
The operator shall not touch output of batteries/adapter and the patient simultaneously.
Manufacturer will make available on request circuit diagrams, component parts list etc.
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 sensization or irritation reaction.Never apply the cuff over hurt skin.
Do not use the unit in case of existing polyester resp. synthetic allergies.
Be careful to strangulation due to cables and hoses, particularly due to excessive length.
Do not connect the air hose to other medical equipment, as this could cause air to be pumped into intravascular systems or high pressure, what could lead to dangerous injuries.
Before use, make sure the device functions safely and is in proper working condition.
Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will been impacted and reduced.
Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorized service centers.
Please report to Manufacturer if any unexpected operation or events occur.
The device doesn't need to be calibrated in two years of reliable service.
Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.
The patient is an intended operator.The patient can measure and change battery under normal circumstances and maintain the device and its accessories according to the user manual.
Don't press or restrict the connection tubing during measurement. The device is not intended for public use.

♥ LCD Display Signal

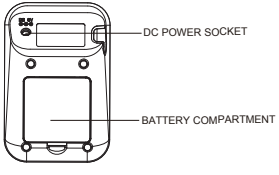


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
PULSE ♡/MIN	Pulse	Pulse/minute
mmHg	mmHg	Measurement Unit of the blood pressure
	Irregular heartbeat	Irregular heartbeat detection
	Battery Indicator	Indicate the current battery
	Grade	The grade of the blood pressure
	Shocking reminder	Shocking will result in inaccurate
	Data transmission error	Data transmission error
	Heartbeat	Heartbeat dectetion during measurement

♥ Monitor Components



Component list of
pressure measuring system
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve



♥ List

1. Blood Pressure Monitor (TMB-1591)

2. Cuff (22cm~42cm) (Type BF applied part)

3. 4*AA alkaline Batteries

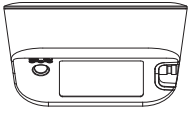
4. User manual

5. AC adaptor (UE08WCP-060100SPA)

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4*AA alkaline batteries
(Notes: A groups of new batteries can be used about 750 times.

2.AC adaptor powered mode:
6V ⎓ 1A
(Can be supplied by AC adaptor model UE08WCP-060100SPA !)
Right picture is the hole in for power adaptor.

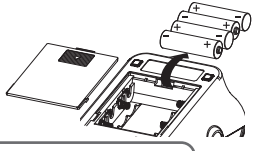


⚠CAUTION

In order to get the best effect and protect your monitor,please use the right battery and special power adaptor. The power adapter is a part of the device. After using, please pull out the adaptor plug insulates from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains.

♥ Installing and Replacing the Batteries

1. Slide off the battery cover.
2. Install the batteries by matching the correct polarity, as shown.
3. Replace the cover.



Replace the batteries whenever the below happen

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

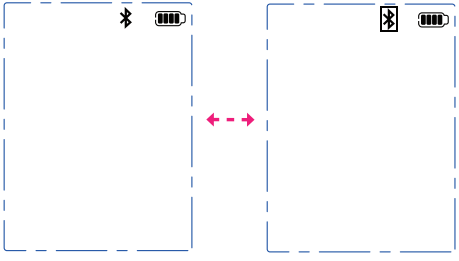
⚠CAUTION

- 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.

♥ Pairing

Turn on Bluetooth and APP. Make sure both are ON when pairing is proceeding.

When the blood pressure monitor is off, press On/Standby button for 2 full seconds to enter bluetooth pairing mode. The symbol flashes, indicating the pairing is proceeding.



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

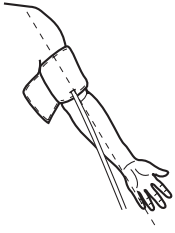
If succeed, symbol will be shown. Then blood pressure monitor will turn off.

If fail, symbol will flash all the time until the blood pressure turns off.

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

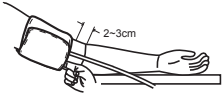
♥ Tie the Cuff

1.Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger.



2.The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.

3.Sit comfortably with your arm resting on a flat surface.



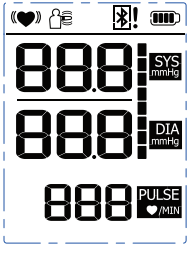
4.Correct position:
- Bare your arm or wear tights only when starting measurement.
- Sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.
The center of the cuff should be at the same level as the right atrium of the heart.

• Rest for 5 minutes before measuring.
• Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
• For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same upper arm, or as directed by a physician.

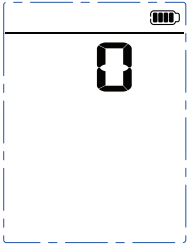
♥ Start Measurement

When the blood pressure monitor is off, press On/Standby button to turn it on, it will finish the whole measurement.

LCD display

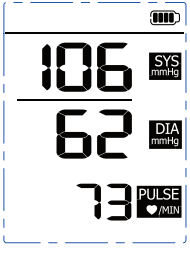


Adjust to zero.

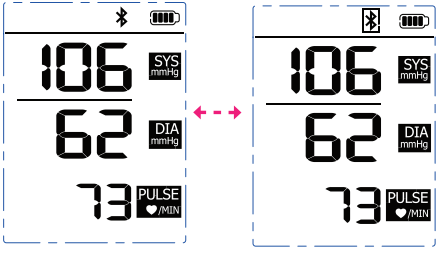


Inflating and Measuring

Display and save the result.



The blood pressure monitor will proceed to data transmission after measurement. The bluetooth symbol flashes on the LCD indicates data is transmitting.



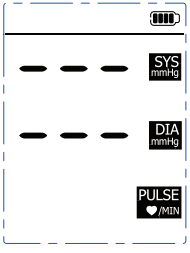
After successful transfer, the device powers off the Bluetooth radio and the icon (and rectangle) are removed.
If the user presses and releases the On/Standby button, another reading is initiated.
If the user presses and holds the On/Standby button for 2 seconds, the device powers down.
Or if there is no operation, after a 10 seconds of inactivity, the device powers down.

Notes: During inflation, the heart icon in the upper left blinks in accordance with the user's pulse rate.
Additionally, during inflation the progress metre to the right of the digits builds vertically up as the pressure increases according to the table below.

Segments	Pressure
1	>= 0
2	>= 40
3	>= 80
4	>= 120

Segments	Pressure
5	>= 140
6	>= 160
7	>= 180
8	>= 200

During the measurement, if you press the On/Standby button to stop the measurement, the numerics are cleared. It will display as below:



If you press and release the On/Standby button, another reading is initiated.
If you press and hold the On/Standby button for 2 seconds, the device powers down.
Or if there is no operation, after a 10 seconds of inactivity, the device powers down.

⚠ 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 oldest record (99) is dropped from the list.

♥ 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

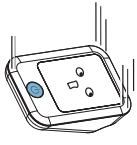
When you want to discharge urine

♥ 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

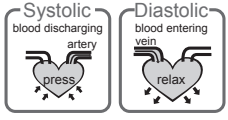
Avoid dusty and unstable temperature environment

Using wet cloths to remove dirt

Avoid washing the cuff

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called 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).

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

AHA Home Guideline for Upper Limit of Normal BP

SYS	135 mm Hg
DIA	85 mm Hg

⚠ 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.

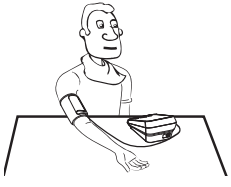
If the cuff is tied on the upper arm.

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 arm?



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

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

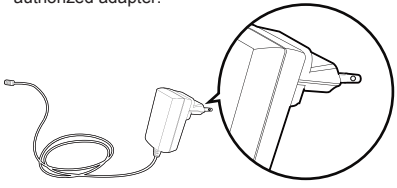
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	The display indicates the “BAT LO” message, pauses for 3 seconds. The battery icon shows empty (does not flash.)	Batteries are low.	Replace with new batteries
Error massage	shows	Unsuccessful pairing.	Check if both the APP and Bluetooth are on, operate and send the data again.
	E 01 shows	The cuff is not secure.	Readjust the cuff and relax for a moment and then measure again.
	E 02 shows	The cuff is too tight or the inflation is too fast.	Refasten the cuff and then measure again.
	E 03 shows	The pressure of the cuff is excess.	Refasten the cuff and then measure again.
	E 10 or E 11 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.
	E 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	Measure incorrectly.	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: 6VDC 4*AA alkaline batteries AC adaptor powered mode: 6V⎓1A (Can be supplied by AC adaptor model UE08WCP-060100SPA !)
Display mode	Digital LCD V.A.68mm*90mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg-300mmHg Measurement pressure: SYS:60mmHg-230mmHg DIA: 40mmHg-130mmHg pulse value:(40-199)beat/minute
Accuracy	Pressure: 5℃-40℃ within±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 106 kPa
Measurement perimeter of the upper arm	About 22cm~42cm
Net Weight	Approx.300g(Excluding the dry cells)
External dimensions	Approx.92mm*140mm*46mm
Attachment	4*AA alkaline batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP20
Software Version	V01

⚠ WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. please use the TRANSTEK authorized adapter.



Adapter
Type: UE08WCP-060100SPA
Input: 100~240V, 50~60Hz,400mA
Output: 6V ⎓ 1A
(Conforms to UL certificate)

♥ 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

♥ 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 IEC60601-1-11:2010
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+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ISO81060-2 Non-invasive sphygmomanometers — Part 2: Clinical validation of automated measurement type
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 62366:2007+A1:2014 IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1 -6 : General requirements for basic safety and essential performance - collateral standard : Usability

♥ FCC Statement

FCC ID: OU9TMB1591-B

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.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

♥ IC Statement

IC ID：**12725A-TMB1591B**

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

♥ 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)