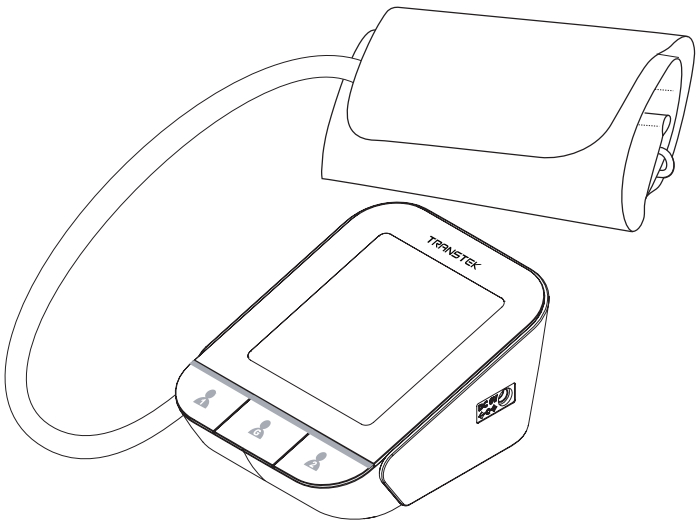
Version:1.0

TRANSTEK

User Manual

Blood Pressure Monitor LS802-E

Arm Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor LS802-E.
- To use the monitor correctly and safely, please read the manual thoroughly.
- please keep well this manual in order to reference in future.

FCC ID:OU9LS802-E02

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TRANSTEK

CATALOGUE

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK arm type blood pressure Monitor (LS802-E). The monitor features blood pressure measurement, pulse rate measurement and the the result storage. The design provides you with two years of reliable service.

Reading taken by the LS802-E 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 instruction for using the product.

Read the manual thoroughly before using the product.

Features:

- 92*78mm Blue LCD display with white backlight
- Maximum 60 records per each user
- Measuring during inflation technology

♥ Safety Information

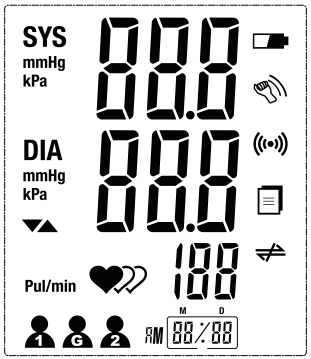
The below signs might be in the user manual, labeling or other component. they are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
	Wireless Transmission		Symbol for “MANUFACTURE DATE”
	Symbol for “MANUFACTURER”		Symbol for “DIRECT CURRENT”
SN	Symbol for “SERIAL NUMBER”		Symbol for “Class II Equipment”
	For indoor use only		Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please follow local guidelines.”
F1	T1A/250V Φ3.6*10CCC		

CAUTION

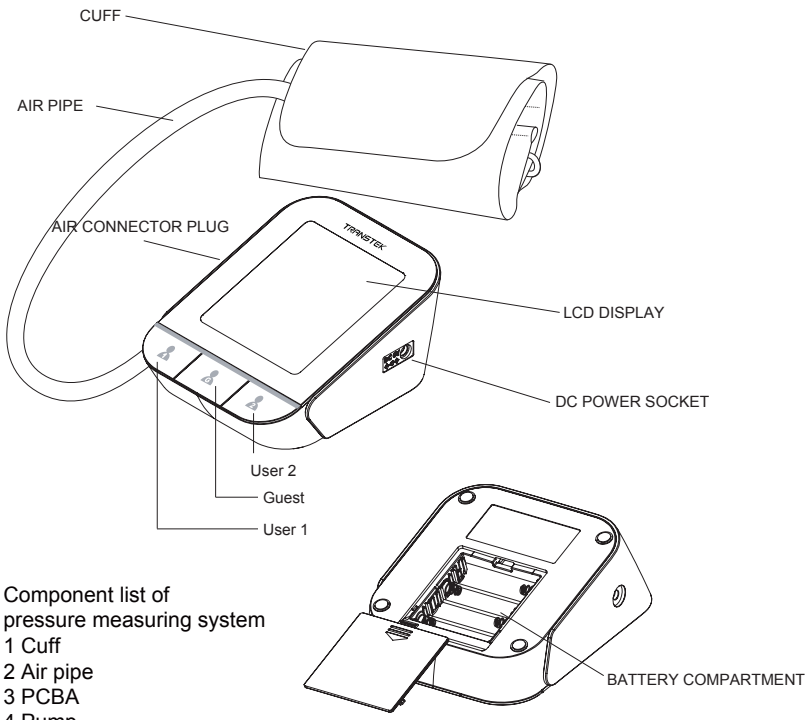
This device is intended for adult use only.
This device is intended for no-invasive measuring and monitoring of arterial blood pressure.
It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment based solely 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.
When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or artrial fibrillation, the best result may occure deviation. Please consult your physician about the result.
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 armand press the START/STOP button to stop inflation.
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 /adapter and the patient simultaneously.
To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical 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.
This device is contraindicated for any female who may be suspected of, or is pregnant. Besides provided inaccurate readings, the affects of this device on the fetus are unknown.
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 arm 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 been impacted and reduced.
During using, the patient will 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 sensization or irritation reaction.
Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
The device doesn’t need to be calibrated in two years of reliable service.
Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of Transtek. Don’t open or repair the device by yourself.
Please report to Transtek if any unexpected operation or events occur.
Please use the soft cloth to clean the whole unit. Don’t use any abrasive or volatile cleaners.
The device has been evaluated clinically used manual cuff/stethoscope ausculation 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
	User 1	Provide measurement for user 1, and then save the measure data
	Guest	Provide measurement for guests, but not save the measurement data.
	User 2	Provide measurement for user 2, and then save the measure data
	Data storage	To remind the users that the measurement data don't upload to bridge in time
	Wireless transmitter	The blood monitor and Bridge in communication
	Network connection	The bridge not connect the network
	Shocking remainding	Shocking will result in inaccurate
	Low battery	Batteries are low and need to be replaced
mmHg kPa	Unit	Measurement Unit of the blood pressure
AM	date (hour:minute)	Currently time
	Deflating	CUFF air is exhausting of deflating
	Arrhythmia	Irregular heartbeat
	Heartbeat	Heartbeat detection during the 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 (LS802-E)

2.Cuff (Type BF applied part) (22~32cm or 22cm~42cm)

3. 4*AA alkaline batteries

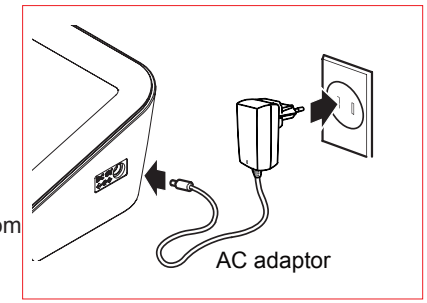
4.User manual

5. AC Adaptor (UE08WCP-060100SPA only!)

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4*AA alkaline batteries

2.AC adaptor powered mode:
100-240V~, 50-60HZ,400mA
(Can be supplied by AC adaptor model UE08WCP-060100SPA only!)



Please unplug the adaptor to depart from the using utility power.

Note:

The adaptor interface is located on the right side of the monitor.

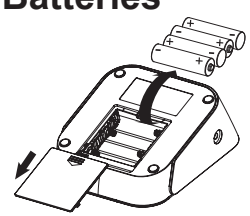
Place NO obstacles on the right for easy pull-off adaptor.

CAUTION

In order to get the best effect and protect you monitor,please use the right battery and special power adapter which complies with U.S. safety standard.

♥ 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

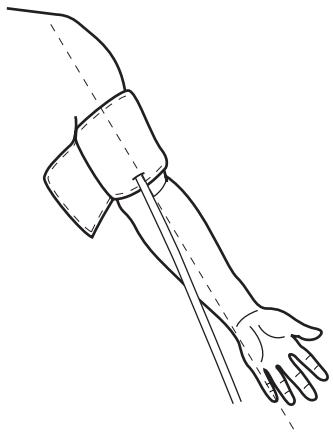
- The + Lo shows
- The display dims
- The display does not light up

CAUTION

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

♥ Tie the Cuff

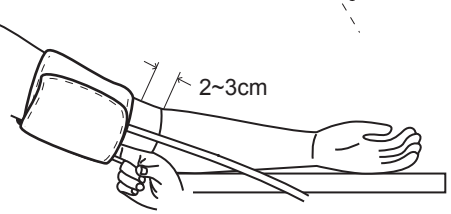
1.Tie the cuff on your upper arm, the position the tube off-center toward the inner side of arm in line with the little finger.



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

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

4.Correct Posture for Patients with Hypertension, especially for Hypertension patient
- 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 central of the cuff should maintain at the same level as the right atrium of the heart.



• Resting 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 arm, or as directed by a physician.

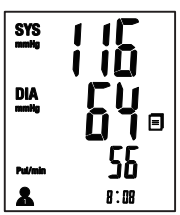
♥ Start the Measurement

Press the User 1 button to turn on the monitor and it will finish the whole measurement, and then save the measure data for User 1. The same to the User 2.
Press the Guest button to turn on the monitor and it will finish the whole measurement for Guest, but not save the measurement data.

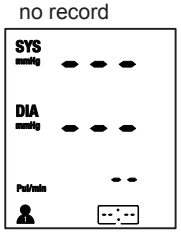
In this manual, the measurement of User 1 as an example.

1. When the monitor is off,
   press the User 1 button to turn on the monitor.

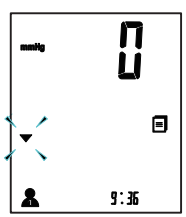
LCD display



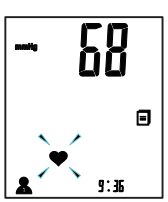
When there is no record



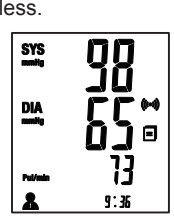
Adjust the zero . If the measure data don't upload to the bridge in time, the icon will display.



Inflating and measuring.



Display and save the results will transmit to the bridge through the wireless.



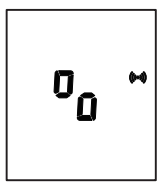
2. Press the User 1 to power off , otherwise it will turn off within one minute.

Tips:

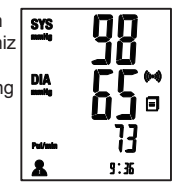
A.when finish the whole measurement, press another button ,the blood monitor will begin measure again.

B.If the blood monitor not connect with bridge, the icon of will display. Maximum 60 records are both for User 1 and User 2.

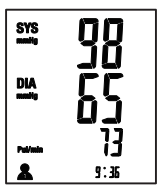
3 Please proceed to activate/synchronize before initial use of this equipment or when the measurement unit is changed. When the equipment is OFF, press and hold "GUEST" button to enter Activation / Synchronization Interface. After successful activation/synchronization, the equipment will display and transmit the measuring results after each measurement.



Activation /synchronization is proceeding



The measurement data is uploading



The data has been uploaded successfully

Wireless Transmission Module No.	AW4431_915	**Supply Voltage**	3.3V
Frequency Range	915 - 918.5 MHz	**Output Power Range**	+1 dBm

CAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol . And LS802-E may interfering vicinity electrical equipment.
- Sensitive people, including pregnant women and those who implanted medical electronic instruments, should avoid using the unit whenever possible.
- Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement.
- To enable the data transmission function, this product should be interconnected with Bridge in RF 915 MHz network.

How to mitigate possible interference?

1. The range between the device and the Bridge should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and the Bridge so as to obtain quality connection and to lower the RF output range.
2. To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

♥ Tips for measurement

It can cause incorrectness if the measurement are taken in the following circumstances.

Within 1 hour
after dinner or drinking

Immediate measurement
after tea, coffee, smoking

Within 20 minutes
after taking a bath

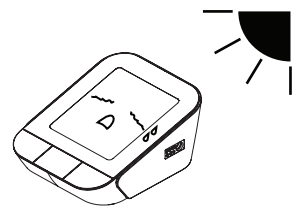
When talking or moving your fingers

In a very cold environment

When you want to discharge urine

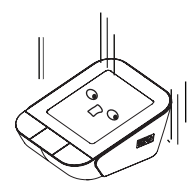
♥ Maintenance

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

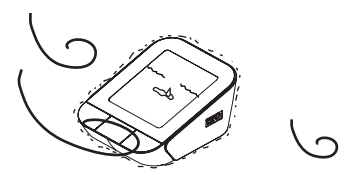


Put in a dry place and avoid the sunshine

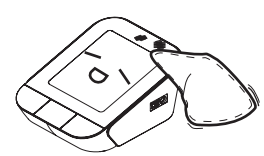
Avoid touching water,
clean it with a dry cloth in case.



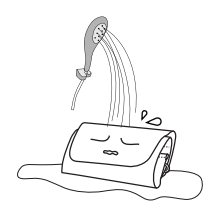
Avoid the intense shaking
and collision



Avoid the dusty and unstable-
temperature environment



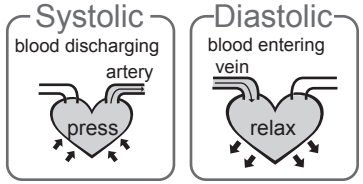
Using the wet clothing to remove the dirt



Avoid washing the cuff

♥ 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. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.

♥ Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. 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, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

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 every in one day, it also affected by the way you tie your cuff and the your measurement position, so please take the measurement at the same condition.

2.The varies of the pressure is greater if the person take medicine.

3.Waiting at least 3 minutes for another measurement.

♥ Why the blood pressure I get from the hospital is different from home?

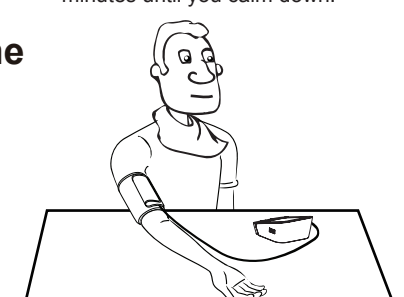
The blood pressure is different even during 24 hour because of the weather,emotion, exercise etc, specially the “white coat” in hospital which makes the results are higher than the ones at home.

The attention need to pay when you measure you 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 pressured.
You had better take deep breath 2-3 times before beginning.
Advice:adjust yourself for 4-5 minutes until you calm down.

♥ If the result is the same if measuring on the right arm?

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



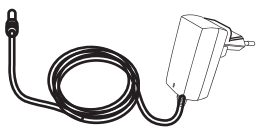
This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

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	Display is dim or show Lo	Batteries are low.	Replace with new batteries
Error massage	E 1 shows	RF communication failed.	Check the database is power on or not. Or synchronize the data operation.
	E 3 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 8 shows	Failure of activating or synchronizing the network	Check if the newwork is connected normally or not.
	E 9 shows	The device is not activated or registered.	Activate or register the device again.
	E10 or E11 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	Exxx,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: 100-240V~, 50-60HZ,400mA (Can be supplied by AC adaptor model UE08WCP-060100SPA only!)
Display mode	Digital LCD V.A.78*92mm
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% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃-60℃ Relative Humidity 10%-93% Atmospheric Pressure: 50-106 kPa
Measurement perimeter of the upper arm	About 22cm~32cm or 22cm~42cm
Net Weight	Approx.385g(Excluding the dry cells)
External dimensions	Approx.120*160*69mm
Attachment	4*AA alkaline batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Device Classification	Battery powered mode: Internally powered ME Equipment AC adaptor powered mode: CLASS II ME Euipment
Software Version	V01

♥ Authorized Components

1. Please use the TRANSTEK authorized adaptor.



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

2.Storage bag.

♥ 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, 5/F., Investment Building , No. 12, Huizhan East Rd., Torch Development District, Zhongshan, Guangdong, 528437, China

♥ 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.

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.

♥ 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
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

♥ EMC Guidance

1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

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)