CE 0123

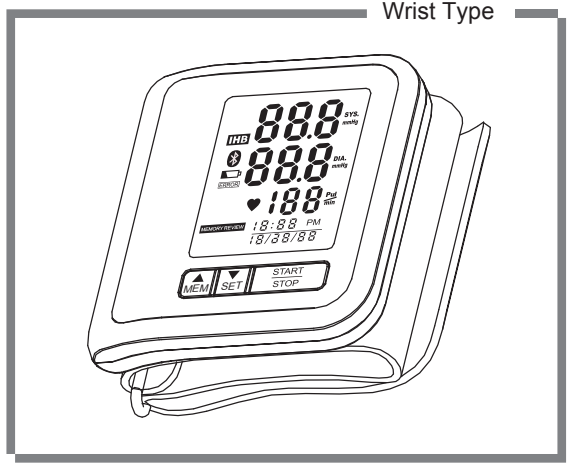
Version:1.0

TRANSTEK

User Manual

Blood Pressure Monitor LS810-B

Wrist Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor LS810-B.
- Please do read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual well for your further reference in case you have problems.

CE 0123 Bluetooth SMART FCC ID: OU9LS810-B01

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
Zone A, 5/F., Investment Building, No. 12, Huizhan East Rd., Torch Development District, Zhongshan, Guangdong, 528437, China

EC REP MDSS - Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK blood pressure Monitor (LS810-B). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of lifetime.

Reading taken by the LS810-B 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.

Please do read this user manual carefully and thoroughly before use.

FEATURES:

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Pulse Rate
- Memory: Up to 60 pieces of records

♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a “zero point” equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate.
The device also compares the longest and the shortest intervals of detected pulse wave to with the average value, and then calculates the standard deviation. The monitor will light up a warning symbol when the calculated standard deviation is larger than or equal to 15.

♥ Safety information

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

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
CE 0123	Symbol for “COMPLIES WITH MDD 93/42/EEC REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION - Wast electrical 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”
Bluetooth SMART	The Bluetooth Combination Mark	EC REP	Symbol for “Authorised Representative in the European Community
	Symbol for “MANUFACTURE DATE”	F1	T1A/250V Φ3.6*10CCC
	Symbol for “ Class II Equipment”		Symbol for indoor use only

♥ Indications for use

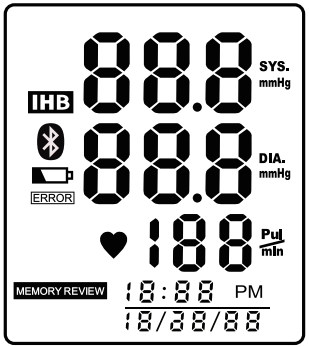
The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5 cm to 21.5 cm (about 5-8.5 inches).

It is intended for adult indoor use only.

CAUTION

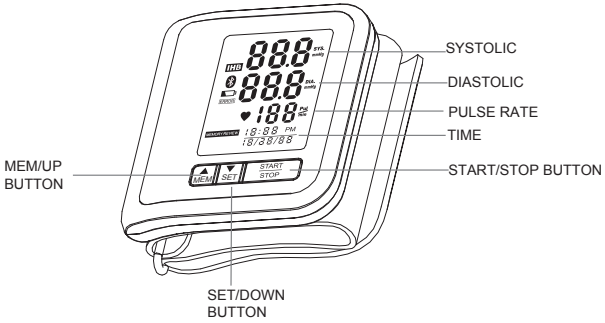
* It is intended for adult indoor use only. Pregnant women, pre-eclamptic patients and patients with severe obesity don’t use the device. If you need, please consult professional doctor.
* This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.
* Please use the device under specified environment by user manual, otherwise the accuracy of the device will be influenced.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Please start or end medical treatment basing solely on physician’s treatment advice.
* If you are taking medication, consult your physician to determine the most appropriate time for your measurement. Never change a prescribed medication without your physician’s consent.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. After the cuff inflated long time, the patient’s wrist and fingers will be blood supply insufficiency, anaesthesia, distending pain and ecchymosis.
* If the pressure of the cuff exceeds 40 kPa (300 mmHg), the unit will automatically deflate. If the cuff don’t deflate when its pressure exceeds 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
* Do not use the monitor under the conditions of strong electromagnetic field (e.g. medical RF equipment) that radiates interference signal or electrial fast transient/ burst signal.
* The maximum temperature that the applied part can be achieved is 42.5 ℃ while the environmental temperature is 40 ℃.
* The device is not AP/APG equipment. It is not suitable for use in the presence of a flammable anesthetic mixture with air (or oxygen, nitrous oxide).
* Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
* Please use ACCESSORIES and detachable parts specified / authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user / patient.
* The patient is an intended operator. The patient can measure, transmit data and charge battery under normal circumstances and maintain the device and its accessories according to the user manual.
* The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to dacron or plastic, please don’t use this device.
* The device is not intended for PATIENT transport outside a healthcare facility.
*This device cannot be used with HF surgical equipment at the same time.
* There is a PTC current limiter in the monitor, which specification is 8V and 0.5A. When the voltage and current exceed the limiting value, the monitor will stop woring.
* The adaptor is specified as a part of ME equipment.
* If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* The device is not suitable for public use.
* The adapter insulates the device from the main supply. Do not position the plug in a position where it is difficult to disconnect from the supply mains.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.

♥ LCD Display Signal

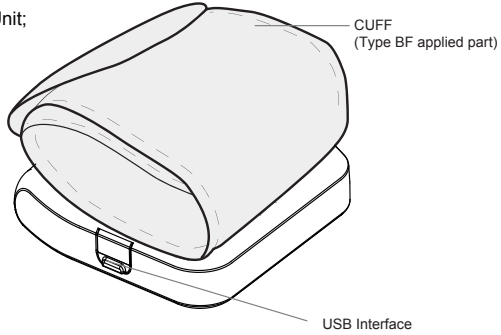


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure
DIA	Diastolic Blood Pressure	Low blood pressure
Pul min	Pulse	beat/minute
+Lo	Low Battery	Low battery and please charge the power.
mmHg	Unit	Measurement unit of blood pressure
IHB	IHB Detector	Irregular Heartbeat Detector
	Bluetooth	Successful Bluetooth Connection
ERROR	Error	Error
MEMORY REVIEW	Memory	Recalling the history records
PM	Time	Hour:Minute (Month/Day/Year)

♥ Monitor Components



Component List:
1. Micro Control Unit;
2. Amplifier;
3. Air Pipe;
4. Pump;
5. Valve.



♥ List

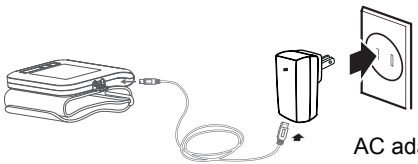
1.Blood Pressure Monitor (LS810-B)

2.USB Cable and AC Adaptor (Model: UE05WCP- 050100SPC)

3.User Manual

♥ Power Supply and Charge Power

1. The battery of LS810-B is built-in rechargeable lithium-ion battery, the battery current is 420 mAh.
2. Please use the AC adaptor and USB cable to charge the battery, just like the following picture:



AC adaptor

Charging the power under following circumstances:

- +Lo displays on the LCD
- The LCD display dims
- When powering on the monitor, the LCD doesn't light up.

CAUTION

1. The battery of LS810-B is built-in rechargeable lithium-ion battery, please do not disassemble it by the unauthorized maintenance personel.
2. Under the normal using, it can charge power about 300 times, if the battery cannot charge the power normally or the blood pressure monitor cannot use normally, please connect with the authorized maintenance personel. If measured three times per day, and the battery is fully charged, it can be used for about 20 days.
3. Storge and use the blood pressure monitor at the cool, dry and ventilated environment. Avoid to approach to the fire and the heat source, or it will cause the battery explode.
4. Only can use the Transtek's authorized AC Adaptor (Model: UE05WCP-050100SPC) to charge the power. You cannot use the blood pressure monitor during the process of charging.
5. During the process of charging, the blood pressure monitor display . When the charging is finished, please pull the plug in time.
6. When charging, shall not touch charging connector and the patient simultaneously.

♥ Setting Date and Time

Please proceed to time setting before your initial use so as to ensure each piece of record are labled with a time stamp. (Year Range: 2012-2052; Time Format: 12 Hours)

1.When the monitor is OFF, press and hold "SET" button for 3 seconds to enter Time Setting Mode.

2.As pictured in the right, the blinking numeral "12" representing [HOUR]. Press "MEM" button to change the numeral. Each press will increase the numeral by one in a cycling manner.

3.Press "SET" button again to confirm [HOUR]. Then the numeral representing [MINUTE] blinks.

4.Repeat step 2 and 3 to confirm [MINUTE].

5.Repeat step 2 and 3 to confirm [MONTH], [DAY] and [YEAR].

7.After confirming [YEAR], the LCD will display “dONE” and the monitor will shut off.

♥ Positioning the Cuff

1.Remove all accessories (watch, bracelet, etc) from your left wrist. If your physician has diagnosed you with poor circulation in your left wrist, use your right wrist.

2.Roll or push up your sleeve to expose the skin.

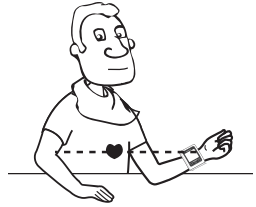
3.Apply the cuff to your left wrist with your palm facing up.

4. Position the edge of the cuff about 1-2 cm.

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.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 arm supported.

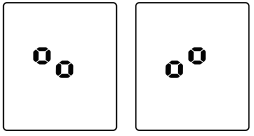
- Resting for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as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



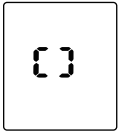
♥ Pair-up the Blood Pressure Monitor with Your Device

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 the START button to start pair-up. The symbol and the symbol will be shown on the LCD alternatively, indicating pair-up is proceeding.



If SUCCEED, symbol will be shown on the LCD.



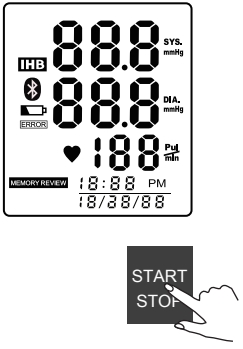
If FAIL, symbol will be shown on the LCD.

3.The monitor will shut off 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 3.6 V
Transmitting Distance: 10 meters

♥ Start Measurement

1.After correctly positioning the cuff, press START button to turn on the monitor, and it will complete the measurement process.



Adjust to zero.

Inflating and measuring.

Display and save the measuring result.

2.This device will proceed to data transmission after measurement.

The Bluetooth symbol blinks on the LCD indicates data is transmitting.

3.If the data is successfully transmitted, the LCD will then display “dONE”.

If the data transmission fails, the LCD will display “ ” instead.

4.Press STOP button to turn off the monitor. Otherwise it will power off.

CAUTION

1. 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 itspressurization 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.
2. Do not apply the cuff over a wound, otherwise it can cause further injury.
3. 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.
4. Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.

CAUTION

5. Don’t link the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT; Sensitive people, including pregnant women pre-eclamptic patients, patients who implanted medical electronic instruments and have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD), should avoid using the unit whenever possible.

♥ Recall the Records

1.Press “MEM” button to access the memory. The monitor will display the calculated average of the last three readings first.

2. Press “MEM/UP” button or “SET/DOWN” button to rotate the history records.
“MEM/UP” to go forward;
“SET/DOWN” to go backward.

CAUTION

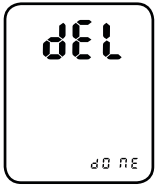
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

♥ Delete the Records

When you did not obtain the accurate measurement, you can clear all the measuring results by following below steps.

1.Under Memory Recalling Mode, press and hold both the “MEM” button and the “SET” button for 3 seconds.

2.The LCD will display “dEL dONE”, indicating that memory clearing is complete.And then it will shutdown.



CAUTION

Under Memory Recalling Mode, if you wish to give up clearing, press “START/STOP” to turn off the monitor.

3.When there is no memory in the monitor, if you press the “MEM” button to look up history, the LCD will display as pictured to the right.

♥ Tips for Measurement

It can cause inaccuracy if the measurement is 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

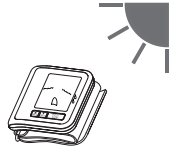
When talking or moving your fingers

In a very cold enviroment

When you want to discharge urine

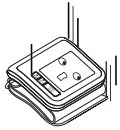
♥ Maintenance

To obtain the best performance, please follow below instructions.



Put in a dry place and avoid the sunshine

Avoid immersing it in the water. Clean it with a dry cloth in case.



Avoid shaking and collision.

Avoid dusty environment and unstable temperature surrounding

Use the slightly damp cloth to remove the dirt.

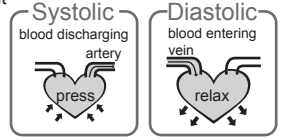
Avoid washing the cuff

CAUTION

1. Please make sure the unit functions safely and it is in proper working conditions before use. Don't service or maintain while the device is in use.
2. 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.
3. Please report to Transtek if any unexpected operation or events occur.
4. Cleaning: Dust environment may affect the performance of the unit. Please use the soft cloth to remove the dirt of the device and cuff before and after use.
5. Calibration: The manufacturer does not require such preventive inspections or calibration by other persons and will make available on request of circuit diagrams, component part list, etc.
6. Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor's failure to power on. Please dispose of ACCESSORIES, detachable parts, and ME EQUIPMENT according to local guidelines.

♥ 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.

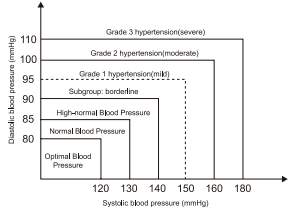


♥ What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:

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.



Blood Pressure (mm Hg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

♥ 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

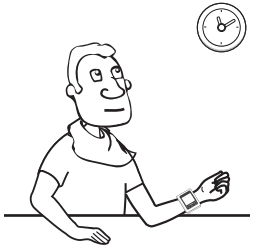
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace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

♥ Why my blood pressure is varies even in one 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?

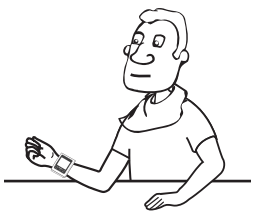
The blood pressure is different even during 24 hour because of the weather,emotion, exercise etc, specially the “white coat” in hospital which makes the results are higher than the ones at home.

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 wrist.
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 wrist?

It is ok for both wrists, but there will be some different results for different person, so 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 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.	Power is exhausted.	Charge the power
Low batteries	+Lo Show on the display	Power is low.	Charge the power
Error massage	shows	Data communication has failed	Make sure that phone’s Bluetooth is on or within the distance range
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E 9 shows	Product has not been activated.	Reactivated
	E 10 or E 11 shows	The monitor detected motion 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	3.7V 420mAH Built-in rechargeable lithium-ion battery, 5V / 1A USB AC Adaptor
Display moder	Digital LCD V.A.46.5x36.5mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kpa-40kpa (0mmHg-300mmHg) Measurement pressure: 4kPa-34kPa (30mmHg-255mmHg) pulse value:(40-199)beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kpa(3mmHg) 0℃-45℃(out of 5℃-40℃) within±0.7kpa(5mmHg) pulse value:±5%
Normal working condition	Temperature:5℃ to 40℃ Relative humidity ≤85% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃ to 60℃ RH: 10% to 93% Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of the wrist	About 13.5cm-21.5cm
Net Weight	Approx.110g
External dimensions	Approx.79.8×72.5×13.2mm
Attachment	USB cable, AC Adaptor,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22, It means the device could protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°
Software version	V01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor charged Mode: Class II ME Equipment

WARNING: No modification of this equipment is allowed.

♥ The Matched Component

1. Please use the TRANSTEK authorized adaptor

Adaptor
Type: UE05WCP-050100SPC
Input: 100-240V, 50-60Hz,0.18A
Output: 5.0V ⎓ 1.0A

♥ 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

Authorized European Representative:
Company: MDSS - Medical Device Safety Service GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

♥ Complied European 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/EN 60601-1: 2006+A1：2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 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 IEC/EN 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
Electromagnetic compatibility	IIEC/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	EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ 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.

EMC Guidance

1.the Blood Pressure Monitor 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 = 3,3 m 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 = 3,3 m at an IMMUNITY LEVEL of 3 V/m)