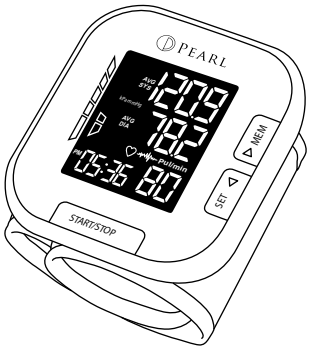
PEARL LEGACY

Vena

Blood Pressure Monitor
TMB-988 User Manual



Thank you for choosing the Vena Blood Pressure Monitor. To use the monitor correctly and safely, please read the manual thoroughly. Please keep this manual well in order to reference in future.

Version 1.0

LifeWithPearl.com

Pearl ® Inc. 120-1231 Burdette Street, Richmond BC Canada, V6V 2Z2

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

CONTENTS

INTRODUCTION 2

- General Description
- Indications for Use
- Safety Information
- Measurement Principle
- LCD Display Signal
- Monitor Components
- List

BEFORE YOU START 8

- Installing and Replacing the Batteries
- Setting Date, Time, Positioning Symbol and Measurement Unit
- Setting the User ID

MEASUREMENT 11

- Tie the Cuff
- Start the Measurement

DATA MANAGEMENT 13

- Recall the Records
- Delete the Records

INFORMATION FOR USER 15

- Tips for Measurement
- Maintenance

ABOUT BLOOD PRESSURE 17

- What are systolic pressure and diastolic pressure?
- What is the standard blood pressure classification?
- Why does my blood pressure fluctuate throughout the day?
- Why do I get a different blood pressure at home compared to the hospital?
- Is the result the same if measuring on the right wrist?

TROUBLESHOOTING 19
SPECIFICATIONS 20
CONTACT INFORMATION 21
FCC STATEMENT 21
COMPLIED STANDARDS LIST 22
EMC GUIDANCE 23

♥ General Description

Thank you for selecting the VENA Blood Pressure Monitor TMB-988.

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 Vena 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, and up to 60 groups of measuring records

♥ Indications for Use

The Vena Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5cm to 21.5 cm (about 5⅓˝-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”
	Symbol for “MANUFACTURE DATE”		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”		
	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”		Symbol for “Recycle”
	The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.		Caution: These notes must be observed to prevent any damage to the device.

♥ 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 25%.

⚠ CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, 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.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* 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.
* 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.
* 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.
* 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: connection tubing kinking 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 side of a mastectomy.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.

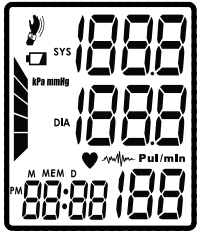
CAUTION

*Do not inflate the cuff on the samb 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.
*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 wrist may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measuring, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* 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.
* When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The maximum temperature that the applied part can be achieved is 42.5℃ while the environmental temperature is 40℃.
* 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.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and change battery under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* 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 sensization or irritation reaction.
* If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.

CAUTION

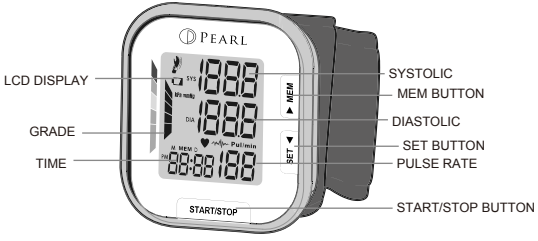
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The operator shall not touch output of batteries and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Pearl. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to Pearl if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is caculated by the MANUFACTURER from the 800 MHz to 2.5 GHz column of Table 6 of IEC 60601-1-2:2007, as appropriate.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no 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.
* 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.

♥ LCD Display Signal



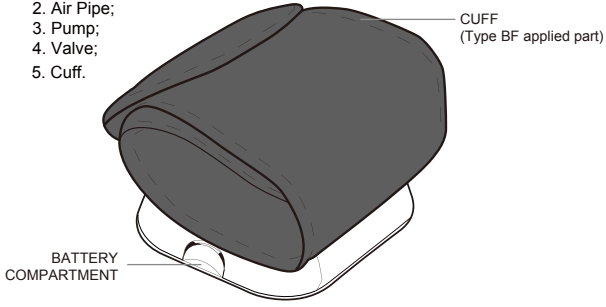
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	Indicates your maximum arterial pressure
DIA	Diastolic blood pressure	Indicates your minimum arterial pressure
Pul/min	Pulse display	Pulse in beats per minute
	Motion indicator	Motion may result in an inaccurate measurement.
+Lo	Low battery	Batteries 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	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Current time	Month/Day,Hour/Minute
	Blood pressure level indicator	Indicate the blood pressure level
♥	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	Memory	Indicate it is in the memory mode and which group of memory it is.

♥ Monitor Components



Component List:

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

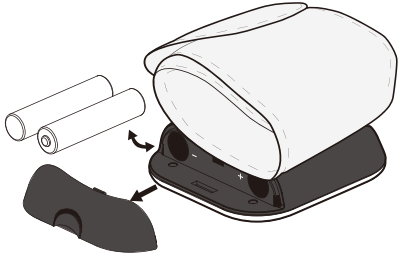


♥ List

1) Wrist Blood Pressure Monitor TMB-988
2) 2×AAA batteries
3) User manual

♥ Installing and Replacing the Batteries

- Slide off the battery cover.
- Install the batteries as indicated in the battery compartment. Always use the correct battery type (2×AAA batteries).
- Replace the battery cover.



Replace the batteries whenever the below happen

- The +Lo shows
- The display is dim
- The display does not light up

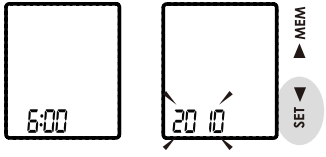
CAUTION

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.

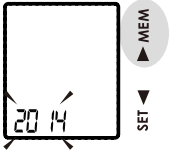
♥ Setting Date, Time and Measurement Unit

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.
(The setting range of year: 2010~2050, time format: 24H/12H)

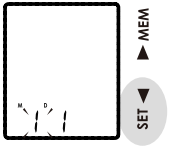
1.When the monitor is off, press"SET" button, it will display the time. Then hold pressing "SET" for 3 seconds to enter the mode for year setting.



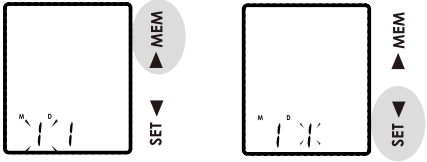
2.Press "MEM" button to change the numeral. Each press will increase the numeral by one in a cycling manner.



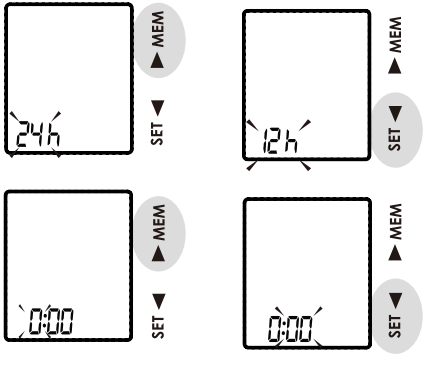
3.When you get the right year, press "SET" button to confirm and it will turn to next step.



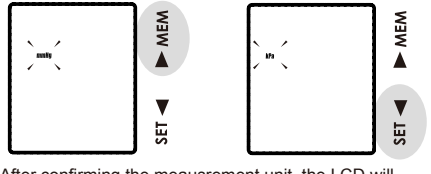
4.Repeat steps 2 and 3 to confirm [MONTH] and [DAY].



5.Then the monitor diverts to time setting. Select the time format.
Repeat steps 2 and 3 to confirm the time format , [HOUR] and [MINUTE].



6.Repeat steps 2 and 3 to confirm the measurement unit.



7.After confirming the meausrement unit, the LCD will display all the settings you have done one by one and then the monitor will shut off.

♥Tie the Cuff

1. Remove all accessories (watch, bracelet,etc) from your wrist. If your physician has diagnosed you with poor circulation in one wrist, use the other wrist for blood pressure measurement.

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 1cm~1.5cm from wrist joints.

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. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.

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.
- Take the measurement in a silent room.
- The patient must relax as much as possible and do not move and talk during the measurement procedure.
- The cuff should be at the same level as your heart.
- Do not cross your legs and keep your feet on the ground.
- Keep your back against the backrest of the chair.
- 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.

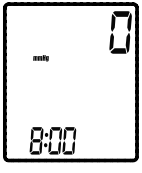
♥ Start the Measurement

1.When the monitor is off, press START/STOP button to turn on the monitor, and it will finish the whole measurement.

START/STOP

LCD display

Adjust the zero.



Inflating and measuring.

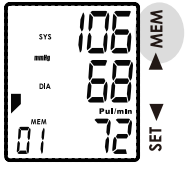
Display and save the result.

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

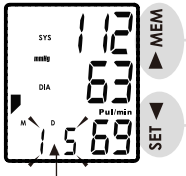
START/STOP

♥ Recall the Records

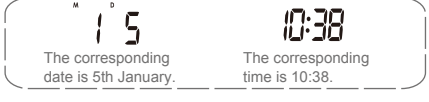
1. When the monitor is off, press “MEM” button to show the latest measurement record.



2. Press “MEM” button or “SET” button to get the record you want.



The date and time will display alternately.



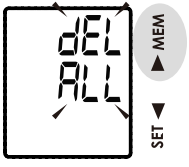
CAUTION

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

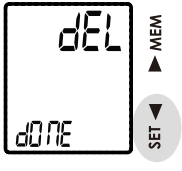
If you did not get the correct measurement, you can delete all results by following steps below .

1. In the memory mode, hold pressing “MEM” button for 3 seconds, the flash display “dEL ALL” will show.

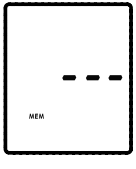


2. Press “SET” button to confirm deleting, the LCD will display “dEL dOnE” and then turn off.

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

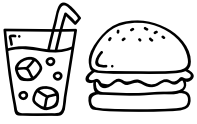


3.If there is no record, the right display will be shown.



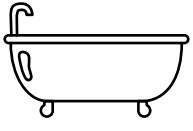
♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

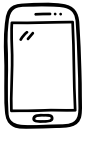


Within 1 hour after eating or drinking

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 instructions below.

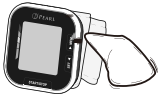
Store in a dry place and avoid direct sunlight

Avoid contact with water, clean it with a dry cloth

Avoid intense shaking and collisions

Avoid dusty and unstable temperature environment

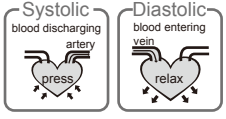
Avoid washing the cuff



Use wet cloths to remove dirt

♥ 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).

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	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	and/or	Higher than 120

⚠ CAUTION

Please consult a physician if your measuring result falls outside 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 (IHB) is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records the heartbeat intervals and calculates the average. If any average is larger than or equal to 25%,the irregular heartbeat symbol will appear on the display.

⚠ 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 differs throughout the day due to weather, emotion, exercise etc. There is the “white coat” effect, which means blood pressure can increase in clinical settings.

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

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

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

If the cuff is secured 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 calm you down and improve measurement.

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 message	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	E 3 shows	The pressure of the cuff is excessive.	Relax for a moment and then measure again.
	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 wrist 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: 2*AAA batteries (3V DC)
Display mode	Digital LCD V.A.35mm×41mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5°C-40°C within±3mmHg(0.4kPa) 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.100g(Excluding the dry cells)
External dimensions	Approx.73mmx67.5mmx22.5mm
Attachment	2*AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22: The first number 2: Protected against solid foreign objects of 12,5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15º. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15º on either side of the vertical.
Software version	V01
Device classification	Internally Powered ME Equipment

WARNING: No modification of this equipment is allowed.

♥ Contact Information

Company: PEARL® Inc.
Address: 120-1231 Burdette Street, Richmond BC, V6V 2Z2

For more information about our products, please visit
www.LifeWithPearl.com

♥ Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2010/ IEC 60601-1-11:2015 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	EN 60601-1-2:2007/ IEC 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 ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability EN 62366:2008/ IEC 62366-1:2015 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304:2006 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

♥ EMC Guidance

1) * This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2) * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) * Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4) * Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Table 1 Guidance and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broad-cast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 6 Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			