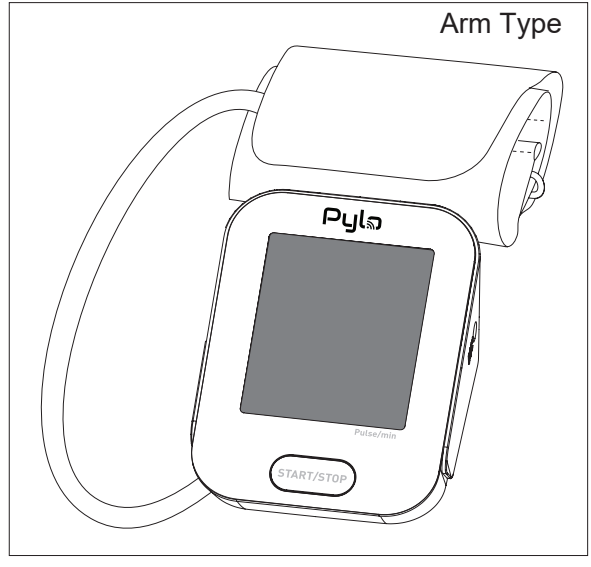
User Manual

LTE Blood Pressure Monitor PY-802-LTE



Thank you for choosing Pylo Health!

This manual outlines how to use your Pylo blood pressure monitor safely and correctly. Please be sure to read it thoroughly and keep it for future reference.

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CATALOGUE

Table of Contents

General Description

Thank you for selecting the Pylo PY-802-LTE arm type blood pressure monitor.
The monitor features blood pressure measurement, pulse rate measurement and digital result storage. Readings taken by the PY-802-LTE 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 read this manual thoroughly before using the product.

Features:
- 78*92mm Digital LCD display
- Measuring during inflation technology
- LTE-M wireless communication

Indications for Use

The Pylo PY-802-LTE is a digital blood pressure monitor intended for use in measuring blood pressure and heartbeat rate on users with an arm circumference ranging from 22cm to 42cm (about 8¾″-16½″).
It is intended for adult indoor use only.

Contraindications

1.The device should not be used by any person who is suspected to be or is pregnant .
2.The device is not suitable for use on patients with implanted electrical devices such as cardiac pacemakers or defibrillators.

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 prior to 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.

Safety Information

The signs below 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”
	Symbol for “MANUFACTURER”		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 “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”		
	Symbol for “RECYCLE”		Symbol for “MANUFACTURE DATE”
	Caution: These notes must be observed to prevent any damage to the device.		

⚠ 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 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 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 is 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.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* 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 arm 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.
*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.
*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure ? 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.

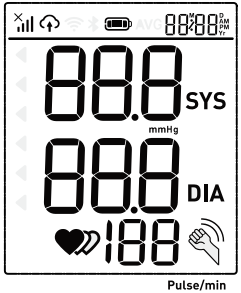
⚠ CAUTION

* 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 arm 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 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, and charge power 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 sensation or irritation reaction.
* Adaptor is specified as a part of ME EQUIPMENT.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press any button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the arm and press any 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!

⚠ CAUTION

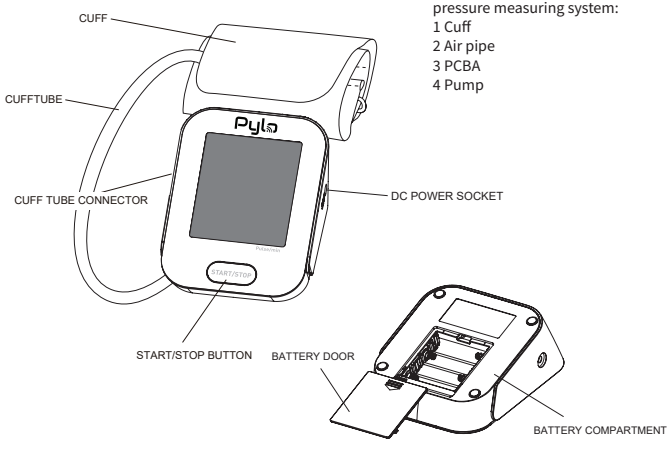
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits 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 plug/adapter plug pins insulate the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
* The operator shall not touch output of batteries /adapter 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 Pylo. 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 Pylo 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, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURER. 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 is 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	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pulse/min	Pulse	Pulse/minute
	Current Time	Time (year:month:day:hour:minute)
	Heartbeat	Heartbeat dectetion during measurement
mmHg	mmHg	Measurement Unit of the blood pressure
	Battery Indicator	Indicate the current battery
	Irregular heartbeat	Irregular heartbeat
	Data transmission indication	Indicates that the data is being sent. oH will show on screen to indicate success.
	Shocking reminder	Sudden movement will result in inaccurate readings
	Signal indication	Indicates the signal situation in the communication process.

Components of the Device



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

Included Parts List

1. Cellular Blood Pressure Monitor (PY-802-LTE)

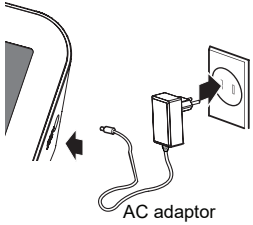
2. Cuff (22~42cm)
(Type BF applied part)

3. User manual

4. Four (4) AA batteries

The Choice of Power Supply

1.Battery powered mode:
6VDC 4*AA batteries
2.AC adaptor powered mode:
6V ⎓ 1A (not included)
(Please only use a manufacturer authorized AC adapter.)
See picture on right hand side for power port location.

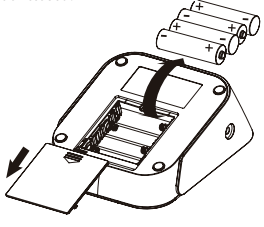


⚠ CAUTION

In order to get the best effect and protect your monitor, please use the the right batteries and special power adapter which complies with local safety standard.

Installing and Replacing the Batteries

If this is your first time using the device:
1.Slide open the battery door on the back of the device.
2.Install the batteries provided with the device. Follow the diagram inside the battery compartment for correct placeme—the springs should align with the negative sign on the batteries.
3.Slide the battery door closed.



Replace the batteries whenever the following occurs:

- The LO+ icon displays
- The display dims
- The display does not light up

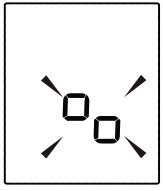
⚠ CAUTION

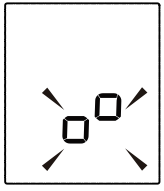
- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Used batteries are harmful to the environment. Do not dispose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

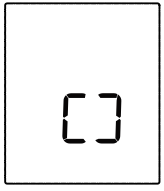
Tip:

When you insert or replace batteries into the device, the symbol and will be shown on the LCD. This indicates that the device is searching and pairing with a mobile network. You can long press " START/STOP " button to end pairing and use the device. If you manually cancel pairing, the device may take longer to send a measurement after use..

When pairing is successful, the symbol is shown on the display. You can then utilize the device as normal by pressing "START".

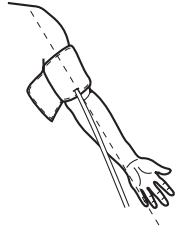


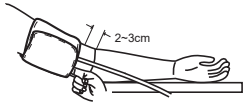


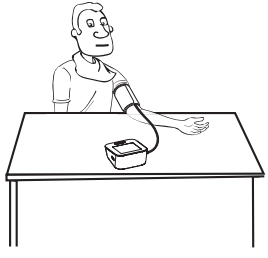


Tie the Cuff

1. Plug the connector into the 'Cuff Port' as labeled on the device.
2. Expose your upper arm by removing or adjusting clothing and jewelry. Make sure blood flow is not constricted by a rolled up sleeve.
3. Open the cuff and loosen fully.
4. Orient the cuff so that the tube exits towards the hand.
5. Place your arm through the cuff loop, with your palm facing up.
6. Position the cuff's edge about an inch (2–3 cm) above the elbow.
7. Align the Φ marker (located to the right of the tube exit) with the center of your arm.
8. Tighten the cuff evenly around your arm by pulling on the end—make sure the Φ marker stays aligned with the center of your arm.
9. Wrap the end of the cuff over your arm to secure it in place. Don't make it too tight—allow a finger to fit between the cuff and your arm.
10. If possible, relax and rest for at least 5 minutes before taking a measurement.
11. Lay your arm on a table with your palm facing up. The cuff should be at the same height as your heart. Sit up straight and rest your feet flat on the ground. Make sure the tube is not kinked or pinched.



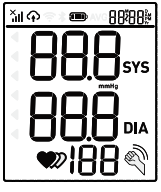




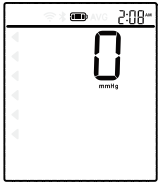
Taking a Measurement

1. When the monitor is off, press the " START/STOP " button to turn on the monitor. The cuff will begin to inflate and the measurement will be taken and saved.

LCD display



Adjust the zero



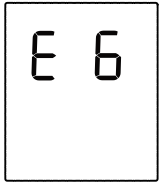
Inflating and measuring

Display and save the results

2. Once measurement is taken, the device will connect to the network and start transmission. The symbol will blink while the device is transmitting.

3.If the data is successfully transmitted, the symbol will disappear and the LCD will display oH before the device turning off.

If the data transmission fails, an error message will be shown (E6 as an example) on the display for several seconds then the device will turn off.



In the case of a data transmission failure (E5 or E6), up to 60 measurements are saved on the device and will be sent when a successful connection is achieved.

Tip:

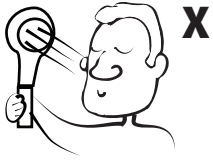
You can press " START/STOP " button at any time to stop measuring during the process of measurement.

Tips for Measurement

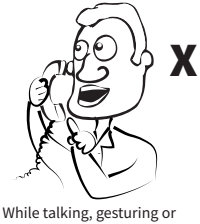
Measurements may be inaccurate if taken in the following circumstances:

Within an hour
after dinner or drinking

After drinking tea, coffee
or using tobacco products.



Within 20 minutes
after taking a bath



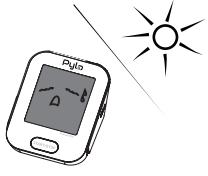
While talking, gesturing or
while in a loud environment.

In a very cold
environment

When you have to go to
the bathroom.

Maintenance

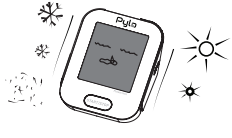
In order to get the best performance, please follow the instructions below.



Store device in a dry place
away from direct sunlight.

Keep away from water. If splashed,
immediately dry with a clean towel.

Avoid shaking or dropping
the device.



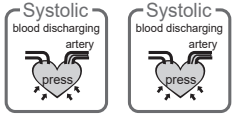
Store device in a place that avoids
quick changes in temperature.

When cleaning device, use a
lightly moist cloth without
soap or detergent.

Do not wash or immerse
the cuff in water.

What are systolic pressure and diastolic pressure?

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



What is the standard blood pressure classification?

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

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

Blood Pressure Category	Systolic mmHg upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	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 Detection

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals, the difference between each interval and the average is more than the average value of ±25% , or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%, then the irregular heartbeat symbol will appear on the display with the measurement 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 throughout the day. It is also affected by the way you tie your cuff and your measurement position. It is important to take measurements in the same conditions.
2. If the person takes medicine, the pressure may vary even more.
3. Wait at least 3 minutes between measurements.

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

The blood pressure is different even throughout the day due to weather, emotion, exercise etc.

Also, there is a phenomenon called the “white coat” effect, which means blood pressure usually increases when measured in clinical settings.

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

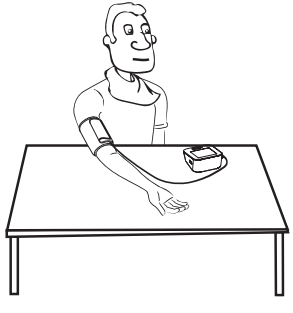
- If the cuff is tied properly.
- If the cuff is too tight or too loose.
- If the cuff is tied on the upper arm.
- If you feel anxious.
- Taking 2-3 deep breaths before beginning will be better for measuring.

Advice:

Relax yourself for 4-5 minutes prior to taking a measurement.

Is the result the same if measuring on different arms?

It is acceptable to use either arm but results might differ between arms for some people.
It is suggested that you measure on the same arm every time.



TROUBLESHOOTING

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

Problem	SYMPTOM	CHECK THIS	REMEDY
No power or Low batteries	Display will not light up or ▭ + Lo show	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
Error message	E 1 shows	The cuff is not secure or inflation is abnormal.	Refasten the cuff and then measure again.
	E 2 shows	The monitor detected motion, talking or the pluse is not readable while measuring.	Movement can affect the measurement. Relax for a moment and then measure again.
	E3 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E4 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	E5 shows	Failed to communicate with the server	Contact customer service
	E6 shows	Radio communication failure	Contact customer service
	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
Warning message	'out' shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

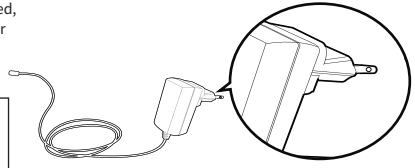
SPECIFICATIONS

Power supply	Battery powered mode: 6VDC 4×AA batteries AC adaptor powered mode: 6V ⎓ 1A (not included) (Please only use the recommended AC adaptor model).
Display mode	Digital LCD V.A.78mm*92mm
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: 5ºC-40ºCwithin±3mmHg(0.4kPa) Pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~42cm
Weight	Approx.393g(Excluding the batteries)
External dimensions	Approx.154.3mm*121.5mm*68.1mm
Attachment	4×AA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software Version	A01

WARNING: No modification of this equipment is allowed.

Authorized Component

If plug in power functionality is desired, only use a Pylo authorized AC adapter (not included).



Adaptor:

Type: BLJ06L060100P-U
Input: 100-240V 50-60Hz,0.2Amax
Output: 6V ⎓ 1000mA

Contact Pylo Health

For more information about our products, please visit www.pylo.com. You can get customer service, usual problems and customer download, Pylo will serve you anytime.

Contact Information: Pylo Health
28632 Roadside Drive
Suite 215
Agoura Hills, CA 91301
info@pylo.com | (818) 600-7162

FCC Statement

contains FCC ID: **XMR2020BG95M2**

This device complies with Part 15 of the FCC Rules. Operation is subject to the 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	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, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ 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 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - 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 80601-2-30:2018 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investi-gation	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+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 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

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning:Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment PY-802-LTE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 3

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles; Single phase: at 0°.0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles; Single phase: at 0°. 0 % U_T; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless commu-nications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						