Blood Pressure Monitor

Instruction Manual

Automatic Upper Arm Style

Model: Prolife PX7 Premium ； Prolife PX6 Advanced

Aim

Artificial inteligente measurement

Need for the user to follow this instruction manual thoroughly for your safety. Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR PHYSICIAN.

IFU- PX7-EN-CB
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Catalogue

1 Introduction

Thank you for purchasing this blood pressure monitor product. This blood pressure monitor uses the oscillometer method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

1.1 Safety Instructions

This instruction manual provides you with important information about the Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of the safety and operating instructions.

If you do not understand these instructions or have any questions, contact your distributor before attempting to use this monitor. For specific information about your own blood pressure, consult with your physician.

1.2 Intended Use

This device is used to measure upper arm systolic blood pressure, diastolic blood pressure and pulse rate.

1.3 Intended users:

Personnel who can operate in accordance with the product user manual, including medical staff and patients.

1.4 Intended patient population

Suitable for adults.

1.5 Intended Use Environment:

The device is intended for use in home and professional healthcare environments.

Operation conditions 5~40℃ 15%~85%RH(non-condensing) 700 hPa~1060 hPa

1.6 Indications:

Monitor the blood pressure and pulse rate of adults.

1.7 Contraindications:

- Do not use this device with a defibrillator.
- Do not use this device during an MRI examination.
- Do not use the device in a flammable environment (i.e., an oxygen-enriched environment).
- Do not immerse the device in water or other liquids. Do not use acetone or other volatile solutions to clean the device
- If you have had a mastectomy, please consult your doctor before using this monitor
- Do not use the monitor in a moving vehicle, such as a car or an airplane
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising, and eating at least 30 minutes before the measurement

1.8 Expected clinical benefit:

Provide a blood pressure monitor with accuracy that meets regulatory requirements for users to measure blood pressure values.

1.9 Introduction to the working principle:

The pressure sensor captures varying cuff pressure and converts it into digital signals for the CPU. The embedded software processes the data via algorithms to determine systolic, diastolic blood pressure and pulse.

2 Important Safety Information

Read the Important Safety Information in this instruction manual before using this monitor. Follow this instruction manual thoroughly for your safety. Keep for future reference. For specific information about your own blood pressure, CONSULT WITH YOUR PHYSICIAN.

2.1 Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- Before using the device, please ensure that you have read this manual thoroughly and fully understand corresponding precautions and risks.
- Do not use this device with a defibrillator.
- Do not use this device during MRI （magnetic resonance imaging） examination.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
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Keep this device and its accessories out of reach of children and individuals who are unable to operate them properly, to prevent hazards such as ingestion of small parts (e.g., batteries) or entanglement with adapter cords and CUFF tubing. Children must not operate the device without supervision.
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Clean the device and cuff with a dry, soft cloth or a cloth dampened with

water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device or cuff.

- During measuring, cuff will be inflated and squeezed the arm hard enough to temporarily stop blood flow through the artery. This may cause pain, numbness or a temporary red mark to the arm. This condition will appear especially when measurement is repeated successively. Any pain, numbness, or red marks will disappear with time.
- People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems.
- Do not repair or maintain the equipment during use to avoid incorrect operation of the equipment and deviation or error of the measured value.
- After inflation, do not twist or knot the CUFF connection hose. Continuous pressure may interfere with blood flow, causing pain, numbness or temporary red marks on the arm due to pressure.
- Do not measure too frequently, which may cause pain and numbness to the user's arm due to obstructed blood flow.
- Do not use a cuff on an arm with a wound as it may cause further injury.
- When CUFF is applied to any limb and pressure is applied, the measurement can be stopped if the pressure temporarily interferes with the flow of blood and may cause numbness in the arm.
- Observe the measured arm during measurement, Immediately power off the device or disconnect the cuff connector to release air if persistent numbness or soreness occurs, to avoid prolonged impairment of limb blood circulation caused by cuff pressurization.
- people with physical, sensory or mental limitations, or those lacking relevant usage experience and knowledge. If such people need to use it, they must operate under the full supervision and usage guidance of the safety supervisor.
- Users with severe limb circulatory disorders should consult a doctor before using this device.
- Do not fold the cuff tubing during inflation. Excess cuff pressure may cause arm discomfort. The unit features automatic overpressure deflation. If the cuff remains pressurized and fails to deflate, power off the device via the power key or disconnect the cuff connector for rapid pressure release.
- Do not use this product with other medical monitoring devices on the same limb at the same time, as the CUFF inflation and compression process may cause temporary functional failure of the monitoring devices used on the same limb.

2.2 Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- If you have had a mastectomy or lymph node removal, talk to your doctor

before using this monitoring device.

- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emit electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage/transport temperature, refer to chapter 11.
- Read and follow the “Correct Disposal of This Product” in chapter 10 when disposing of the device and any used accessories or optional parts.
- DO NOT insert batteries with their polarities incorrectly aligned.

2.3 General Precautions

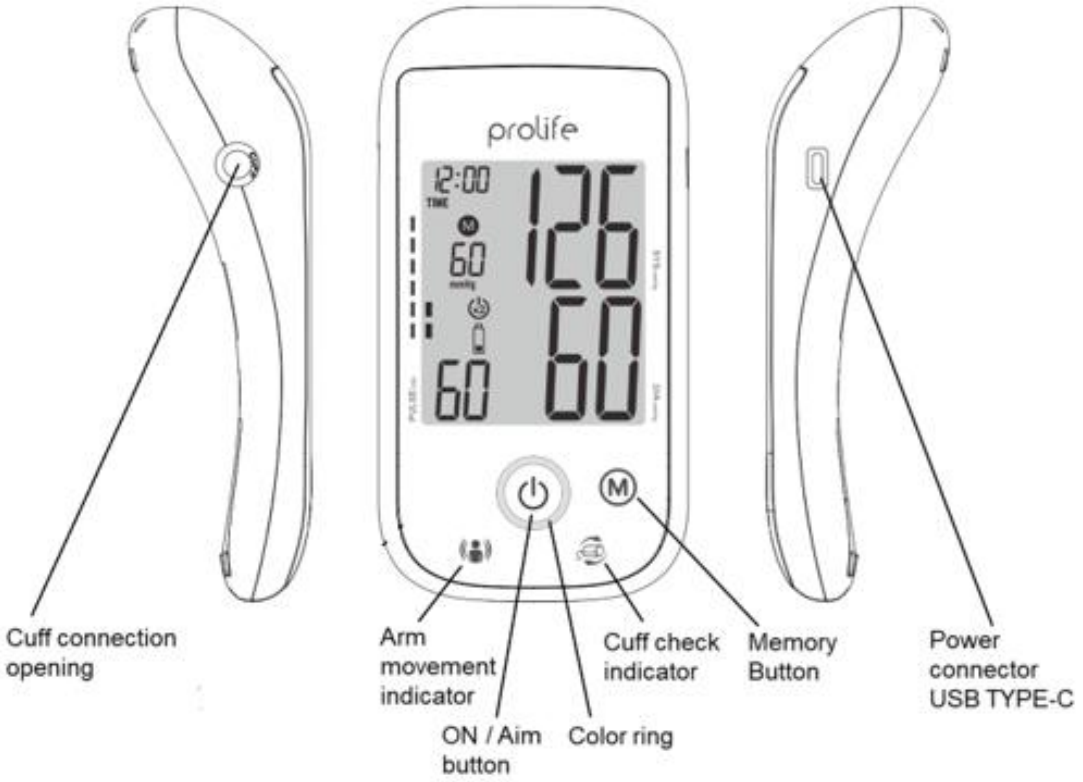
- To stop a measurement, press the [ON] button while taking a measurement.
- When you take a measurement on the left arm, the air tube should be at the side of your elbow. be careful not to rest your arm on the air tube.
- Blood pressure may differ between the right and left arm, and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.

3 Know your device

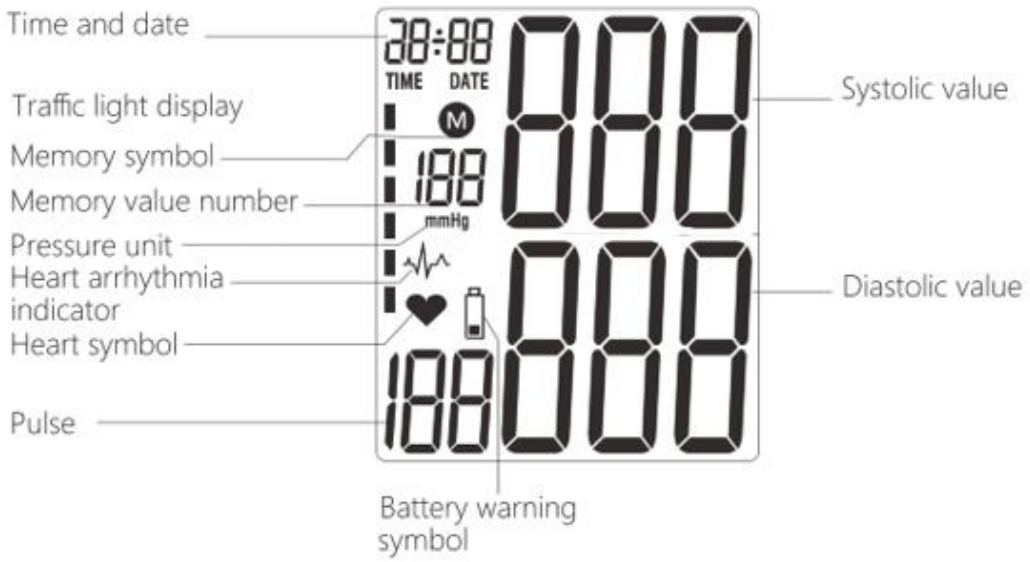
3.1 Operating key:

- ON / Aim Button : turn on & setting
- MEMORY Button: check memory

COMPLETENESS



3.2 Adopt digital LCD display



3.3 Common Functions:

1) Blood pressure and heart rate are measured
2) Memory storage and clearing functions
3) Date and time Settings

Note: The above basic normal functions can be safely used by the operator.

3.4 Functional Description

Low Battery Warning:

If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out.

If the battery warning icon appears in the display, the batteries are empty and must be replaced by new ones

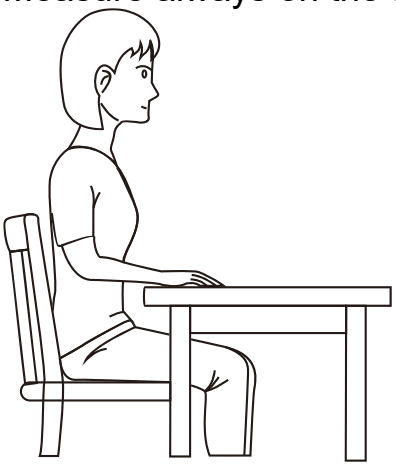
Attention! After the battery warning icon appears, the device is blocked until the batteries have been replaced.

3.5 Preparing for a Measurement

30 minutes before avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quite atmosphere for about ten minutes before the measurement.

5 minutes before: Relax and rest

Measure always on the same arm (normally left).



4 Preparation before use

Please check the complete accessories before using this product.

Final assembly includes this battery installed (see chapter 4.1) and cuff wearing (see chapter 5.1)

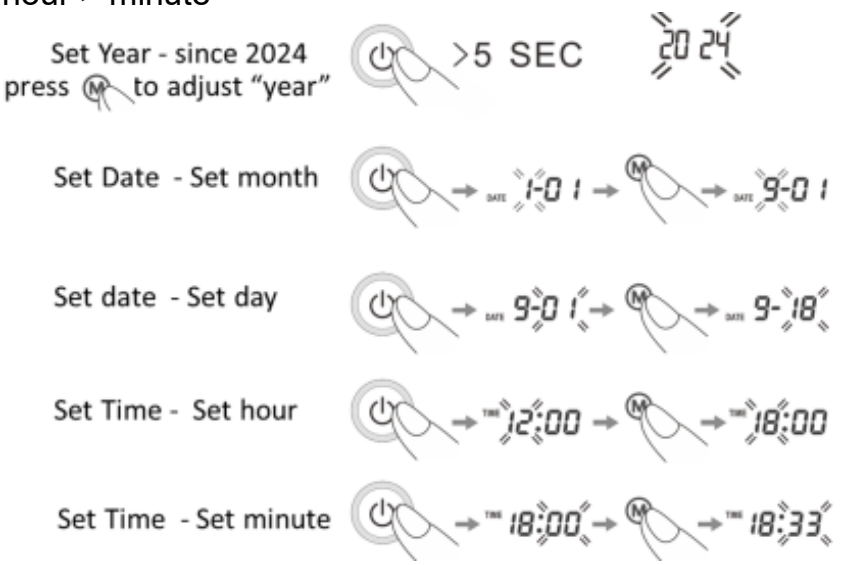
4.1 Installing Batteries

1) Insert the batteries (4 x size AAA 1.5V), thereby observing the indicated polarity.
2) If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out.
3) If the battery warning icon appears in the display, the batteries are empty and must be replaced by new ones

1) Attention! •After the battery warning icon appears, the device is blocked until the batteries have been replaced.
2) Please use «AAA» Long-Life or Alkaline 1.5V Batteries. The use of 1.2V Accumulators is not recommended
3) If the blood pressure monitor is left unused for long periods, please remove the batteries from the device.

4.2 Setting Date and Time

Please press ON button to turn on device
Press and hold ON button 5 seconds entering into setting mode
and year, date , time will be shown in the display. Set year > month > day > hour > minute



All setting completed , then press ON button for the setting confirmation then device enters to sleep
If no button is pressed within 30 seconds,
the device saves the setting value and enters to sleep

4.3 How to connect to the power Supply

This product can use either batteries or an AC adapter (optional) as its power supply.

1) How to use the AC adapter (with USB connector)

- Plug the USB connector into the main unit's power supply inlet.
- Plug the AC adapter into an electric outlet.

2) General Recommendations

- Please unplug the AC adapter after use. Do not leave it connected to the power

supply for a long time.

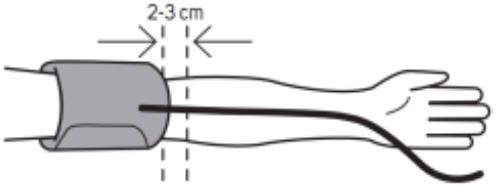
5 Use equipment

5.1 Applying the Arm Cuff

Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day

1) Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Do not place the arm cuff over thick clothes.
2) Insert the air plug into the air connector securely

3) Tube side of the cuff should be 2 - 3 cm above the inside elbow. Make sure that air tube is on the inside of your arm and wrap the cuff

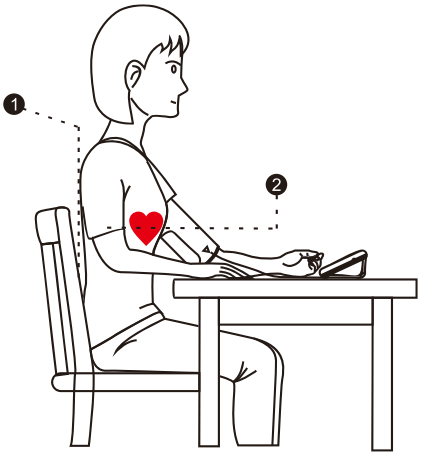


Notes:

- When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube.
- The blood pressure can differ between the right arm and the left arm, and the measured blood pressure values can be different, and recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician which arm to use for your measurements.

5.2 Sitting Correctly

1) Sit comfortably with your back and arm supported
2) Place the arm cuff at the same level as your heart.
3) Keep feet flat, legs uncrossed, remain still and do not talk.
4) The sphygmomanometer is placed in a position that the user can normally operate, and the blood pressure reading displayed after the measurement is completed is not affected in any way.



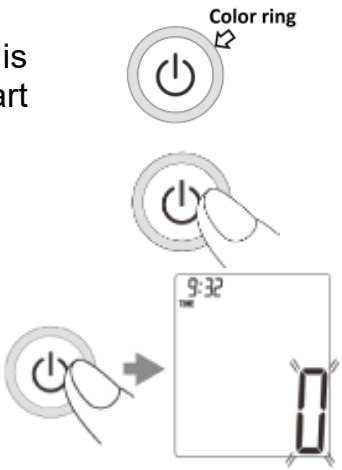
5.3 Taking a Measurement

Measuring procedure

Measuring in standard mode

In this mode, an indication of pulse wave arrhythmia is possible. When the cuff is securely fixed, you can start measurement:

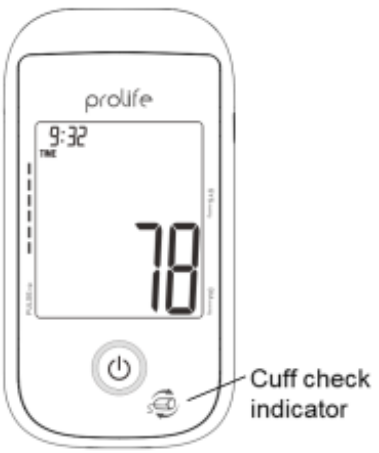
1. Press “ON” button to turn-on device , then “**color ring**” will turn green color
2. Press “ON” button again , then pump begins to inflate the cuff. during this time, the cuff pressure values are continuously displayed.



Cuff fitting detection:

if cuff fit too loose, the icon will light during measuring.

If cuff fit well, the icon will not light



Cuff too loose ,
Cuff check indicator will light up

arm movement detection

the icon will appear, if a movement was detected which may influence accuracy. If the movement is not too serious, the measuring can be continuous

if the movement is too serious,
Err2 displayed

As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation. when the device detects the pulse in the inflation , the heart symbol in the display begins to blink for every pulse beat.

Arm movement indicator
If movement detected ,
Arm movement indicator will light up

Measurement examples measured in standard mode

Measurement results

example 1

Example 1: (Fig. 2):
Systole 120,
Diastole 80,
Pulse 70,
and arrhythmia detected,
cuff fit well.

example 2

Example 2: (Fig. 3):
Systole 120,
Diastole 80,
Pulse 70,
and arrhythmia detected,
cuff fit too loose.

example 3

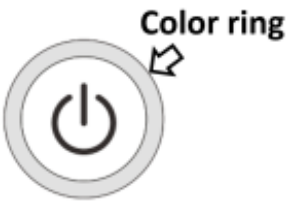
Example 3: (Fig. 4):
Systole 128,
Diastole 86,
Pulse 68,
and a movement detected,
cuff fit well.

Color ring definition :

According to 2023 ESH Guidelines of WHO for Classification of hypertension

Category	Color of Color ring	Systolic (mmHg)	Diastolic (mmHg)
Optimal	Green	<120	<80
Normal	Orange	120-129	80–84
High- Normal	Orange	130-139	85–89
Grade 1 hypertension	Red	140–159	90–99
Grade 2 hypertension	Red	160–179	100–109
Grade 3 hypertension	Red	≧180	≧110
Isolated systolic hypertension	Red	≧140	≦90
Isolated diastolic hypertension	Red	≦140	≧90

An additional definition for color ring :
Even if it is green according to WHO classification , it must be Green flashing if IHB, too loose cuff fit , arm movement are detected during measuring



Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the “ON/OFF” power button can be pressed at any time.

The device then immediately lowers the cuff-pressure automatically.

5.4 Using Memory Functions

1) Reading Memory:

The blood-pressure monitor automatically stores each of the last 199 measurement values. By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement and the further last 198 measurements (MR199, MR198, ..., MR1) can be displayed one after the other.

MA:
Average value of
the last 3 measurements

M3:
measurement value
of memory 3

M6:
measurement value
of memory 6

2) Deleting All Memories

Before you delete all readings stored in the memory, make sure you will not need refer to the readings at a later date. Keeping a written record is prudent and may provide additional information for your doctor's visit. In order to delete all stored readings, depress the MEMORY button for at least 5 seconds, the display will show the symbol «CL» and then release the button. To permanently clear the memory, Press the MEMORY button while «CL» deletes stored readings.

5.5 Bluetooth function

1) Open the Bluetooth APP on your mobile phone.
2) Turn on the blood pressure monitor device. After pressing the start measurement button, the Bluetooth module will automatically turn on.
3) For the first time pairing Bluetooth, click on "Add Bluetooth" in the APP, find the Bluetooth name and add it.
4) After the blue module successfully connects to the mobile phone APP, the time and date of the blood pressure monitor will be automatically synchronized and updated.
5) After the blood pressure monitor completes the measurement, the DIA, SYS, and PUL data will be automatically uploaded to the mobile phone APP.

6 Useful Information

What is Blood Pressure?

Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart's cycle.

The highest pressure in the cycle is called the Systolic Blood Pressure; the lowest is the Diastolic Blood Pressure. Both pressures, the Systolic and Diastolic, are necessary to enable a physician to evaluate the status of a patient's blood pressure.

What is Arrhythmia?

Arrhythmia is a condition where the heartbeat rhythm is abnormal due to flaws in the bio-electrical system that drives the heartbeat. Typical symptoms are skipped heartbeats, premature contraction, an abnormally rapid (tachycardia) or slow (bradycardia) pulse.

How do I evaluate my blood pressure?

The indicated lines on the left-hand edge of the display points at the range within which the measured blood pressure value lies. The value is either within the optimum, High- Normal or hypertension range. The classification corresponds to the following ranges defined by international guidelines (2023 ESH). Unit in mmHg

Classification of hypertension:

These values are provided by the 2023 ESH Guidelines for the management
The BP category is defined by the highest level of BP, whether systolic or diastolic.

Isolated systolic or diastolic hypertension is graded 1, 2 or 3 according to SBP and DBP values in the ranges indicated. The same classification is used for adolescents ≧16 years old.

Category	Systolic (mmHg)	Diastolic (mmHg)
Optimal	<120	<80
Normal	120-129	80–84
High- Normal	130-139	85–89

Grade 1 hypertension	140–159	90–99
Grade 2 hypertension	160–179	100–109
Grade 3 hypertension	≧180	≧110
Isolated systolic hypertension	≧140	≦90
Isolated diastolic hypertension	≦140	≧90

Further information
If your values are mostly standard under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so–called «labile hypertension». This condition also requires correction, please consult a doctor.

IMPORTANT FACTS ABOUT ATRIAL FIBRILLATION (AFIB)
What is atrial fibrillation (AFIB)? Normal heart functions rhythmically, alternating the phases of contraction and relaxation.
Specialized cardiac muscle cells (so-called cardiac conduction system) generate electrical pulses which make the heart contract by «pushing» the blood into the vessels. Atrial fibrillation occurs in the event of impaired functioning of the cardiac conduction system and the appearance of disorganized electrical signals in the atria, causing their irregular contraction (fibrillation). Atrial fibrillation is the most common form of cardiac arrhythmia or irregular heartbeat. Atrial fibrillation may be asymptomatic, but significantly increases the risk of stroke. This case requires medical supervision.

How does AFIB impact my family or me?
People with AFIB have a five-fold higher risk of getting stroke. Since the chance of having a stroke increases with age, AFIB screening is recommended for people over 65 years and older. Persons aged over 50 with high blood pressure (diagnosed with hypertension), diabetes, cardiac distress and prior stroke also need timely diagnosis of atrial fibrillation. In young people AFIB screening is not recommended as it could generate false positive results and unnecessary anxiety. In addition, young individuals with AFIB have a relatively low risk of getting stroke as compared to elder people.
ADVANCE AFIB detection provides a convenient way to screen for AFIB. Knowing your blood pressure and knowing whether you or your family members have AFIB can help reduce the risk of stroke. ADVANCE AFIB detection provides a convenient way to screen for AFIB whilst taking your blood pressure. Risk factors you can control High blood pressure and AFIB are both considered «controllable» risk factors for strokes. Knowing your

blood pressure and knowing whether you have AFIB is the first step in proactive stroke prevention.

7 Error Messages and Troubleshooting

If any of the below problems occur during measurement, check to make sure that no other electrical device is within 30 cm. If the problem persists, please refer to the table below.

Error No.	Possible cause(s)
ERR 1	No pulse has been detected.
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the Measurement (Artefact).
ERR 3	The inflation of the cuff takes too long. The cuff is not correctly seated.
ERR 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take another reading following directions carefully. Contact you doctor if you continue to get unusual readings.
ERR 8	CUFF pressure >290 mmHg

Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1.Check batteries for correct polarity and if necessary insert correctly. 2.If the display is unusual, re-insert batteries or exchange them.
The device frequently fails to measure the blood pressure values, or the values measured are too low (too high).	Check the positioning of the cuff. Measure the blood-pressure again in peace and quiet under observance of the details made under point 5.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal	Repeat the measurement. Please note: Blood pressure fluctuates continually so successive measurements will show some variability.
Blood pressure measured differs from those values measured by the doctor.	Record the daily development of the values and consult your doctor. Please note: Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at

	the doctor than obtained at home under resting conditions.

8 Maintenance

Users can perform the following maintenance operations on the device, but pay attention to the precautions mentioned in each maintenance item.

8.1 Maintenance

To protect your monitor from damage, follow the directions below:
Changes or modifications not approved by the manufacturer will void the user warranty.

Caution DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

8.2 Storage

Properly store the blood pressure monitor main unit and all accessories when not in use..

1) Detach the cuff from the main unit.
2) Fold the air tube neatly and tuck it inside the cuff.
3) Place the main unit, cuff and other accessories into the dedicated storage case, or keep them in a clean, stable and safe area.

Caution!

- To disconnect the cuff connector, grip the plastic connector at the base of the air tube. Do not pull the air tube directly.
- Do not bend the CUFF tube too much. At the same time, keep the CUFF away from sharp objects to prevent it from being scratched or punctured by sharp objects, which may cause air leakage.
- Do NOT store the device and accessories under the following conditions:

- When the device or accessories are wet.
- In areas with extreme temperature or humidity, direct sunlight, dust, or corrosive fumes such as bleach.
- In locations prone to vibration, impact or dropping.

8.3 Cleaning

Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and arm cuff, and then wipe them with a dry cloth.

The following operations are prohibited:

- Do not use any abrasive or volatile cleaners.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and arm cuff or other components.

8.4 Battery replacement and maintenance：

1) When the device shows that the battery is low, please replace the battery in time.
2) When the battery is installed on the product and is not used for a long time (about 1 week), it should be taken out in time for separate storage.

Note: The installation of the battery is detailed in section 4.1 of this manual.

8.5 Calibration and Service

- The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorized dealer or the Customer Service at the address given on the packaging or attached literature.

8.6 Optional Medical Accessories

Arm cuff：22~32cm(M-size cuff) or 22~42cm (M-L size cuff)

9 Limited Warranty

Thank you for purchasing this product. This product is constructed of high quality materials and great care has been taken in its manufacturing.
It is designed to give you every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.
This product is guaranteed for 3 years from the date of purchase. During this warranty period, defective products or any defective parts can be repaired or replaced free of charge. However, product problems caused by any of the following are not covered by the warranty.

1) Transport costs and risks of transport.
2) Costs for repairs and / or defects resulting from repairs done by unauthorized persons.
3) Periodic check-ups and maintenance.
4) Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
5) Costs arising due to non-acceptance of a claim (those will be charged for).
6) Damages of any kind including personal caused accidentally or from misuse.
7) Calibration service is not included within the warranty.
8) Optional parts have a one (1) year warranty from date of purchase. Optional parts include, but are not limited to the following items: cuff and cuff tube.

For warranty service, please apply to the dealer where you purchased the product. For address, please refer to the product package/instructions or your specialty retailer.
Repair or replacement within the warranty period shall not result in any extension or renewal of the warranty period.
Warranty is only available if the complete product is returned together with the original invoice/cash ticket issued to the consumer by the retailer.

10 Correct Disposal of This Product

(Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life.

To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

11 Technical specifications

Product description	Blood Pressure Monitor
Product category	Electronic Sphygmomanometers
Model	Prolife PX7 Premium ； Prolife PX6 Advanced
Display	LCD digital display
Cuff pressure range	0 to 290mmHg
Blood pressure measurement range	SYS：60 to 255 mmHg DIA：40 to 195 mmHg
Static accuracy	Pressure: ±3 mmHg
Pulse	Pulse measurement range ： 40 to 199 beats / min ±5% of display reading
Measurement method	Oscillometer corresponding to Korotkoff method: Phase I: systolic, Phase V: diastolic
IP classification	IP20
Inflation	Automatic by electric pump
Deflation	Automatic pressure release valve
Applied part	Type BF (arm cuff)
Power supply interface	⎓ 5V/1A
Mode of operation	Single automatic measurement
Power source:	4*1.5V “AAA” alkaline Batteries
Durable period (Service life)	Monitor: 5 years battery life: about 500times cuff and adapter life: 5 years
Operation conditions	5~40°C 15%~85%RH(non-condensing) 700 hPa~1060 hPa
Storage/transport conditions	-10~55°C 10%~95%RH(non-condensing) 500 hPa ~1060 hPa
Protection against electric shock	CLASS II and INTERNALLY POWERED

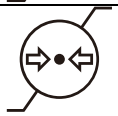
Dimensions:	Monitor: 172 x 99 x 49 ±1.0 mm
Weight:	Monitor: approximately 420 g (not including batteries) Arm cuff: approximately 170 g
Accessories:	Cuff: circumference 22~32cm (M-size cuff) or 22~42cm (M-L size cuff). 4 "AAA" batteries, instruction manual ,warranty card, AC adapter
Contents	**device, cuff, user manual, warranty card**
Memory	1 x 199 memories for 1 users (SYS, DIA, Pulse)
Optional Accessories	AC adapter DC5V/1A; USB power cord 1.5m
Bluetooth	operating frequency 2.4GHz ISM band, Radio Power 3dBm

Note

1) These specifications are subject to change without notice.
2) This monitor is clinically investigated according to the requirements of (AAMI/ESH/ISO)" 2019 - (ISO 81060-2:2018) in the clinical validation study, .
3) IP classification is degrees of protection provided by enclosures in accordance with IEC 60529.
4) users can buy the adapter in the market which must comply to EN60601-1, EN60601-1-2 and EN60601-1-11 ;It is recommended to use the factory-configured adapter, model: TAP5-050S100E3. The manufacturer is TOKPOWER ELECTRONICS CO., LTD.

12 Symbols Description

Symbols	Description	Symbols	Description
EU REP	Authorized representative		Applied part - Type BF
CE 0197	CE Marking of Conformity Announcement number institutions		Electrical and electronic equipment marks
LOT	Batch code		Refer to instruction manual/ booklet
IP20	Ingress protection degree provided by IEC 60529		General warning sign
	Date of manufacture		Caution
SN	Serial number		Manufacturer

Symbols	Description	Symbols	Description
	Medical device		Unique device Identifier(UDI)
	Direct current		Warning! Not suitable for children under 3 years old
	Catalogue number		Importer
	Humidity limitation		Temperature limit
	Atmospheric pressure limits		Distributor
	Fragile, handle with care		This way up
	Stacking limit by number		Keep dry
	Keep away from sunlight		CUFF tightness detection (optional)
	Cuff Connector		Movement detection (optional)

13 Guidance and Manufacturer's Declaration

Important Information Regarding (EMC)

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Our medical devices comply with IEC60601-1-2 in terms of immunity and emissions.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Blood Pressure Monitor use RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The Blood Pressure Monitor 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity			
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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	±2kV for power supply	±2kV for power supply	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV	±0.5 kV, ±1 kV	
Voltage dips, short interruptions	0 % UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°,	0 % UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°,	Mains power quality should be that of a typical commercial or hospital

and voltage variations on power supply input lines IEC 61000-4-11	225°, 270° and 315° 0 % UT, 1 cycle and 70% UT, 25/30 cycles at 0° 0% UT, 250/300 cycle	225°, 270° and 315° 0 % UT, 1 cycle and 70% UT, 25/30 cycles at 0° 0% UT, 250/300 cycle	environment. If the user of the Blood Pressure Monitor requires continued operation during power mains interruptions, it is recommended that the Blood Pressure Monitor p be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields/ Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	CW 8A/m for 30kHz Pluse modulation 2.1kHz,65A/m for 134.2MHz Pluse modulation 50kHz,7.5A/m for 13.56MHz	CW 8A/m for 30kHz Pluse modulation 2.1kHz,65A/m for 134.2MHz Pluse modulation 50kHz,7.5A/m for 13.56MHz	
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity

The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that they are 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 6 Vrms in ISM bands and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands and amateur radio bands	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 Blood Pressure Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	

	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	

Shenzhen Combei Technology Co., Ltd.
11-5B, No.105, Huanguan South Road, Dahe Community,
Guanhu Street, Longhua District,Shenzhen,
518110 Guangdong
P.R. China

EU REP MedNet EC-REP GmbH,
Borkstrasse 10, 48163 Münster, Germany

Incident Reporting Notice
Per EU MDR 2017/745 and equivalent rules, EU users and patients shall immediately report any serious incident related to product use to the manufacturer, its authorised representative and local competent authority of the EU Member State concerned.