prolife

INSTRUCTION MANUAL
DIGITAL BLOOD PRESSURE MONITOR
Model: Prolife PX7 Premium (BP136A)*

en

IM-PX7PREMIUM-EN-V01
Issue date: 2024-09-12

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.

* In the text of the instruction manual, abbreviated name of device is used: Digital Blood Pressure Monitor Prolife PX7 Premium.

CATALOGUE

1 INTRODUCTION

Medical device name

Digital Blood Pressure Monitor **Prolife PX7 Premium (BP136A)***.

Thank you for choosing the **Prolife PX7 Premium** automatic Blood Pressure Monitor (hereafter referred to as "Blood Pressure Monitor"). This device uses the oscillometric method to measure blood pressure, detecting the movement of blood through the brachial artery and converting it into digital data for result display.

The **Prolife PX7 Premium** Blood Pressure Monitor is equipped with Prolife AIm technology, which uses artificial intelligence to analyze blood pressure, heart rate, and detect atrial fibrillation (AFIB) from the very first measurement cycle to optimize the measurement experience of the next following second and possible third measurement. Measurement comfort and accuracy will be significantly improved.

The **Prolife PX7 Premium** device features the unique Prolife AFIB Smart technology, which allows early detection of atrial fibrillation – a dangerous heart rhythm disorder closely related also to high blood pressure. Atrial fibrillation often occurs without symptoms but significantly increases the risk of stroke and heart failure in elderly, or in patients with risk factors such as high blood pressure, diabetes, or heart failure. AFIB Smart technology works in conjunction with Prolife AIm technology.

It significantly enhances the sensitivity and specificity of atrial fibrillation detection, which is crucial for the regular screening of atrial fibrillation.

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 Blood Pressure 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 Blood Pressure Monitor. For specific information about your own blood pressure, consult with your physician.

*In the text of the instruction manual, abbreviated name of device is used: Digital Blood Pressure Monitor **Prolife PX7 Premium**.

1.2 Intended Use

The Blood Pressure Monitor is designed for use by both healthcare professionals and home users. The device is a non-invasive system developed for measuring systolic and diastolic blood pressure, as well as pulse rate in adult patients. The measurement is performed using an inflatable cuff that is placed around the upper arm.

1.3 Intended users

Medical staffs or patients who can use the product according to the Instruction Manual.

1.4 Intended patient population

The Blood Pressure Monitor is designed for use by both healthcare professionals and home users. This device is suitable for adult.

Consult with your physician before using this Blood Pressure 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, rambling, or shivering may affect the measurement reading.

1.5 Intended Use Environment:

The Blood Pressure Monitor is designed for use by both healthcare professionals and home users. Operation conditions 5~40 °C, 15%~85% RH (non-condensing), 700 hPa~1060 hPa.

1.6 Indications:

Displays the measurement results of the diastolic and systolic blood pressures and pulse rate of an adult individual.

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 device.
- Do not use the device 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.

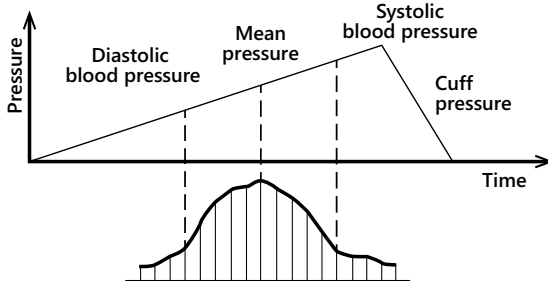
1.8 Expected clinical benefit

Providing 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 device uses oscillometer method to measure blood pressure with the method of measuring during inflation.

Working principle: the device uses an air pump to inflate the cuff and press the artery blood vessel with the inflatable cuff. With the pressure increase in cuff, the arterial vessels showed a change process of completely opening – gradually opening – completely blocking. During the process of blood pressure inflation, the amplitude of intra-arterial pressure changes as shown in the figure below:



the pressure sensor collects the pressure amplitude changes in the cuff, converts it into a digital signal and sends it to the CPU. The embedded software is used to analyze and identify the corresponding pressure points in the process of arterial blood flow obstruction to determine the diastolic, systolic and mean blood pressure of the human body.

2 IMPORTANT SAFETY INFORMATION

Read the Important Safety Information in this instruction manual before using this Blood Pressure 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 place this device in pressure vessels or gas sterilization device.
- 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 device 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.

This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.

- 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.
- Blood Pressure measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should consult your doctor immediately if you experience symptoms that could indicate acute disease.
- 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.

- It is not possible to use this device to diagnose illness or diseases. This is exclusively the responsibility of your doctor.
- 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.
- To measure blood pressure, the arm must be squeezed by the cuff 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 device during use to avoid incorrect operation of the device and deviation or error of the measured value.
- The measurement procedure checks the CUFF tube. Do not twist the CUFF tube to avoid the pressure of the CUFF causing pain, numbness, or temporary red marks on the user's arm.
- 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.
- By observing that there are no obvious symptoms of discomfort in the limb, the operation of the Blood Pressure Monitor will not cause long-term damage to the patient's blood circulation.

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 device or other property.

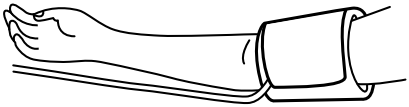
- Stop using this Blood Pressure Monitor and consult with your physician if you experience skin irritation or discomfort.
- If you have had a mastectomy or lymph node removal, talk to your doctor before using this monitoring device.
- ONLY inflate the arm cuff when it is applied on your upper arm.
- Remove the arm cuff if it does not start deflating during a measurement.

- DO NOT use this Blood Pressure 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 Blood Pressure Monitor. This may result in incorrect operation of the Blood Pressure Monitor and/or cause an inaccurate reading.
- DO NOT use this Blood Pressure Monitor in a moving vehicle such as in a car or on an aircraft.
- DO NOT use this Blood Pressure Monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation 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 Blood Pressure 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 Blood Pressure Monitor to warm up or cool down when the Blood Pressure 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/transportation temperature, refer to section 12.
- During measurement, the cuff should be avoided from being interfered with by extrusion or other external forces, and it should only be used on people whose arm circumference is within the specified range of the cuff.
- Use only cuffs with specified specifications, use of other cuffs may result in incorrect readings. (See Section 8.6 of this manual for cuff specifications).
- Read and follow the "Correct Disposal of This Product" in section 10 when disposing of the device and any used accessories or optional parts.
- DO NOT insert batteries with their polarities incorrectly aligned.

- ONLY use 4 "AAA" alkaline or manganese batteries with this Blood Pressure Monitor.
- DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove batteries if this Blood Pressure Monitor will not be used for a long period of time.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
- DO NOT use batteries after their expiration date.
- Periodically check batteries to ensure they are in good working condition.

2.3 General Precautions

- To stop a measurement, press the **ON/OFF** button while taking a measurement.
- When you take a measurement on the right arm, the air tube should be at the side of your elbow. Be careful not to rest your arm on the air tube.

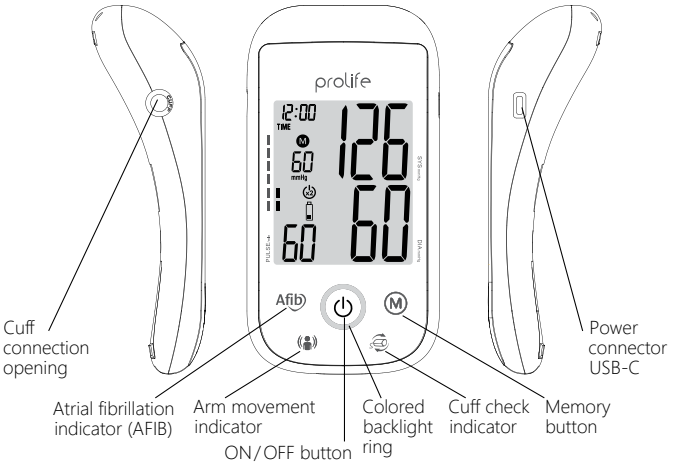


- Blood pressure may differ between the right and left arm, and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.

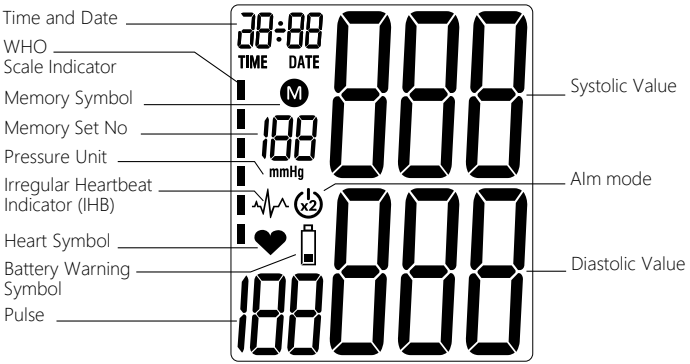
3 KNOW YOUR DEVICE

3.1 Operating key

- **ON/OFF** Button: turn on/off, setting**.**
- **MEMORY** Button: check memory and clear measurement values, setting.



3.2 Digital LCD display description



3.3 Common Functions:

- Blood pressure and heart rate are measured.
- Memory storage and clearing functions.
- Date and time Settings.

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

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.

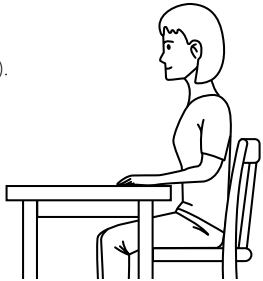
3.5 Preparing for a Measurement

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 section 4.1) and cuff wearing (see section 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.

Attention!

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

Please use «AAA» Long-Life or Alkaline 1.5V batteries. The use of 1.2 V batteries is not recommended.

If the Blood Pressure Monitor is left unused for long periods, please remove the batteries from the device.

4.2 Setting Date and Time

This Blood Pressure Monitor incorporates an integrated clock with date display. This has the advantage, that at each measurement procedure, not only the blood pressure values are stored, but also the exact moment of the measurement.

After new batteries have been inserted, the clock begins to run **TIME** 12:00 and **DATE** 1–01.

You must then re–enter the date and current time. For this, please proceed as follows.

Setting Date and Time

Please press **ON / OFF** button to turn on the device.

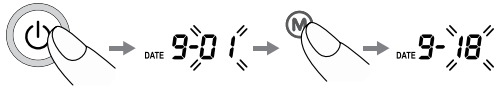
1. Press and hold **ON / OFF** button 5 seconds entering into setting mode. Indicator «Year» will blink. The correct year (since 2024) can be entered by pressing the **MEMORY** button.

2. Press the **ON/OFF** button again. The display now switches to the current date, during which the first character (month) blinks. The corresponding month can now be entered by pressing the **MEMORY** button.

Set Month

3. Press the **ON/OFF** button again. The last two characters (day) are now blinking. The corresponding day can now be entered by pressing the **MEMORY** button.

Set Day



4. Press the **ON/OFF** button again. The display now switches to the current time, during which the first character (Hour) blinks. The corresponding hour can now be entered by pressing the **MEMORY** button.

Set Hour

5. Press the **ON/OFF** button again. The last two characters (Minutes) now blink. The exact time can now be entered by pressing the **MEMORY** button.

Set Minute

6. All setting completed , then press **ON/OFF** button for the setting confirmation. The device enters to the sleep mode.

   If no button is pressed within 30 seconds, the device saves the setting value and enters to the sleep mode.

Additional information

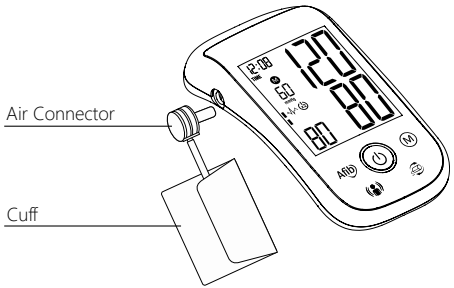
With each press of the button (**MEMORY**) one input is made (altering the value by +1). However, if you keep the respective button depressed, you can switch more quickly to find the desired value respectively.

5 USE EQUIPMENT

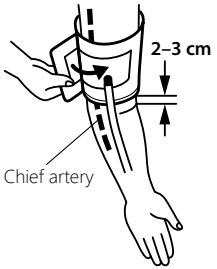
5.1 Applying the Arm Cuff

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 Connector into the Cuff connection opening securely.



3. Fix the cuff with Velcro fastener so that it lies comfortably and fits snugly to your arm. 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.



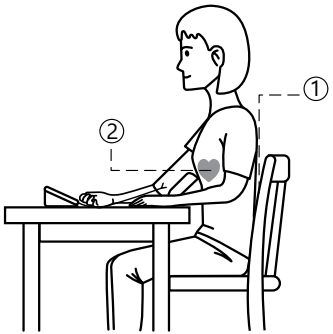
Notes:

- 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 Blood Pressure Monitor 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.



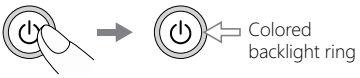
5.3 Taking a Measurement

Measuring procedure

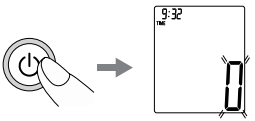
Measuring in standard mode

In this mode, an indication of IHB and AFIB is possible. When the cuff is securely fixed, you can start measurement:

1. Press **ON/OFF** button to turn-on device, then "colored backlight ring" will turn green color.



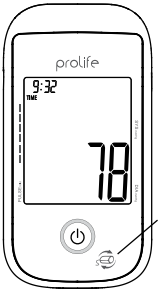
2. Press the **ON/OFF** button again, the pump begins to inflate the cuff. During this time, the cuff pressure values are continuously displayed.



3. Stay at rest. The device measures blood pressure during inflation of the cuff.

Cuff fitting detection.

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

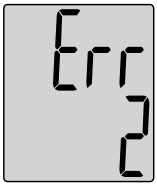


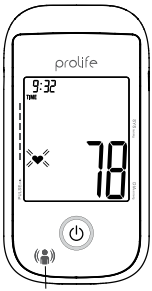
Cuff too loose,
cuff check indicator will light up

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.

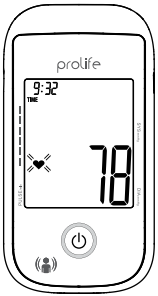




Arm movement indicator
If movement detected
Arm movement indicator
will light up

4. As the cuff inflates, the device automatically determines your ideal inflation level. This device 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.

5. When the measurement has been concluded, the measured systolic and diastolic blood pressure values as well as the pulse frequency are now displayed.



Measurement examples measured in standard mode:

Measurement results

Example 1:
Systolic pressure 120,
Diastolic pressure 80,
Pulse 70,
and arrhythmia detected
cuff fit well.

Example 2:
Systolic pressure 120,
Diastolic pressure 80,
Pulse 70, and arrhythmia
detected, cuff fit too
loose.

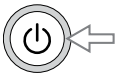
Example 3:
Systolic pressure 128,
Diastolic pressure 86,
Pulse 68,
and a movement
detected,cuff fit well.

Colored backlight ring definition:

According to 2023 ESH Guidelines of WHO for Classification of hypertension

Category	Color of Colored backlight 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 colored backlight ring:
Even if it is green according to WHO classification, it must be yellow if IHB, too loose cuff fit, arm movement are detected during measuring.



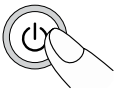
When the AFIB is detected, the ring is always red.

Measuring in the AIm technology mode.
Detection of atrial fibrillation (AFIB) in AFIB Smart mode.

In this mode, powered by artificial intelligence, the device performs 2 to 3 measurements, with each subsequent measurement becoming more comfortable and smooth. The combined data, after analyzing the signals of measurement cycle is leading to highest objectiveness and accuracy. Additionally, the device utilizes AFIB Smart Technology, which significantly increases (improves) the sensitivity and specificity in detecting atrial fibrillation.

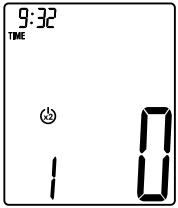
When the cuff is properly fixed, you can start measurement:

1. Press **ON / OFF** button to turn-on device, then "Colored backlight ring" will turn green color.

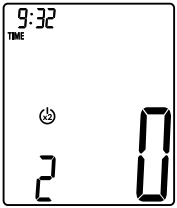


2. Press and hold the **ON / OFF** button more than two second until the symbol ⏻ appears on the display, the pump begins to inflate the cuff. During this time, the cuff pressure values are continuously displayed.

3. Stay at rest. The device measures blood pressure during inflation of the cuff. During measurement a number 1, 2 or 3 is shown on the left-hand side of the display, depending on which of the two consecutive measurements is currently being performed.



4. The interval between measurements is 15 seconds (complies with requirements of «Blood Pressure Monitoring, 2001, 6:145-147» for oscillometric instruments). There is a countdown function.



5. The results of the first measurement will not be displayed. The blood pressure values will be displayed only after 2 measurements. Do not remove the cuff from the arm for the entire duration of the consecutive measurements.
   In some cases, the third measurement may be automatically performed to obtain the exact result.

Measurement examples measured in AIm technology mode:

Measurement results

Example 1:
Systolic pressure 128,
Diastolic pressure 86,
Pulse 68,
AFIB detected.
Icon of arrhythmia and AFIB icon Afib blink,
arm movement detected,
cuff fit too loose detected.

Example 2:
Systolic pressure 128,
Diastolic pressure 86,
Pulse 68,
arrhythmia detected,
but no AFIB detected.
Arm movement detected
and cuff fit well.

The measurement results are displayed until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off.

Appearance of the atrial fibrillation indicator for early detection.

This device is able to detect atrial fibrillation (AFIB). This icon Afib indicates that atrial fibrillation was detected during the measurement. If atrial fibrillation is detected, it is recommended to repeat the measurement again. If AFIB symbol Afib appears after repeated measurement, you are advised to wait for one hour and perform the measurement one more time. If the AFIB symbol appears on the display after a pause of 1 hour, you are advised to consult a doctor. If after repeated measurement the AFIB symbol is no longer displayed, there is no cause for concern.In this case, it is recommended to measure again the next day.

Keep the arm still during measuring to avoid false readings. This device may not detect atrial fibrillation in people with pacemakers or defibrillators.

Appearance of the arrhythmia indicator (IHB detection).

This symbol indicates that certain pulse irregularities were detected during the measurement. In most cases, this is no cause for concern (for example, with the so-called respiratory arrhythmia, which is a normal irregularity). However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily), you are advised to inform your doctor.

Please show your doctor the following explanation.

This device is an oscillometric Blood Pressure Monitor that also analyses pulse frequency during measurement. The device is clinically tested. The arrhythmia symbol is displayed after the measurement, if pulse irregularities occur during measurement.The device does not replace a cardiac examination by ECG, but serves to detect rhythm disturbance at an early stage.

The measurement results are displayed, until you switch the device off or the device switches automatically off, to save the batteries.

However, anytime later the results can be recalled from the device memory. For details see item 5.5.

When the measurement results are as follows:

- Measurement results display error provided, please follow the instructions in section 7 to exclude.
- If the measurement results are significantly off, please re-measure or consult your doctor.

5.4 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.

5.5 Using Memory Functions

Memory. Storage and recall of the measurements

The Blood Pressure Monitor automatically stores the 199 last 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.

M[A]: average value of the last 3 measurements

M[3]: measurement values of memory 3

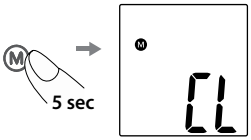
M[6]: measurement values of memory 6

M[8]: measurement values of memory 8

Deleting All Readings

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.



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.

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. AFIB Smart 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. AFIB Smart detection provides a convenient way to screen for AFIB while 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.

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)
Hypotension	<100	<60
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

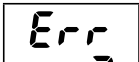
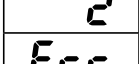
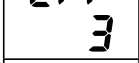
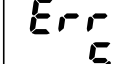
Further information

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.

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)
	The device can not determine the value of the pulse

	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the Measurement (Artefact)
	The inflation of the cuff takes too long. Incorrect cuff placement or replace the cuff
	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
	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 device 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 device or other components. This may cause an inaccurate reading.

8.2 Storage

Keep your device in the storage case when not in use.

1. Remove the arm cuff from the device.

⚠ **Caution**

To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.

2. Gently fold the air tube into the arm cuff. Note: Do not bend or crease the air tube excessively.
3. Place your device and other components in the storage case.

- Store your device and other components in a clean, safe location.
- Do not store your device and other components:
  - If your device and other components are wet.
  - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
  - In locations exposed to vibrations or shocks.

8.3 Cleaning

Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your device 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 device and arm cuff or other components in water.

- Do not use gasoline, thinners or similar solvents to clean your device 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 printed materials.

How to enter to test mode

(ONLY FOR AUTHORIZED SERVICE SPECIALISTS):

⚠ This function is only for professionals to enter the pressure calibration mode of the electronic sphygmomanometer and check the pressure value of the electronic sphygmomanometer through a standard pressure meter Test method.

- Press and hold **ON/OFF** button while battery was installed, then "CA" and "0" will be displayed.

8.6 Optional Medical Accessories

- Prolife standard cuff 22–32 cm;
- Prolife standard cuff 22–42 cm;
- Prolife conic cuff 22–42 cm;
- Prolife conic cuff 22–45 cm.

9 LIMITED WARRANTY

The Digital Blood Pressure Monitor **PX7 Premium** has a 10 years warranty from the date of purchase. The warranty does not apply to damage caused by improper handling, accidents, not following the operating instructions or alterations made to the device by third parties.

The warranty is valid only in the presence of a warranty card, completed by an official representative, confirming the date of sale and cash receipt. Information on the warranty for consumables, parts and accessories is indicated in the warranty card.

Warranty and free of charge service is not performed when:

- use of the device in violation of the instruction manual;
- in case of damage as a result of deliberate or erroneous actions of the consumer due to improper or negligent treatment;
- the presence of traces of mechanical impact, dents, cracks, chips, etc., on the body of the device, traces of the opening of the casing, disassembly, traces of attempts to repair outside the authorized maintenance center, traces of moisture ingress or aggressive agents, or any other foreign interference in the construction of the device, as well as in other cases of violation by the consumer of the rules for storage, cleaning, transportation and technical operation of the device, provided in the instruction manual;
- penetration of oils, dust, insects, liquids and other foreign objects inside the device.

Precisely follow the instructions to ensure reliable and long-term operation of the device.

For repair and maintenance, please contact a specialized after-sales service.

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 MANUFACTURER INFORMATION

Contact information

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

EU representative information

EC REP **Authorized Representative in the European Union:**
MedNet EC-REP GmbH, Borkstrasse 10, 48163 Münster, Germany.

12 TECHNICAL SPECIFICATIONS

Product description	**Digital Blood Pressure Monitor**
Product category	**Electronic Sphygmomanometers**
Model	**Prolife PX7 Premium (BP136A)**
Display	LCD digital display
Cuff pressure range	0 to 290 mmHg
Blood pressure measurement range	SYS: 60 to 255 mmHg DIA: 30 to 199 mmHg
Static accuracy	Pressure: ±3 mmHg
Pulse	Pulse measurement rang: 40 to 199 beats/min ±5% of display reading
Measurement method	Oscillometric 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, USB-C
Mode of operation	Automatic single measurement or multiple measurement
Power source:	4x1.5V AAA alkaline batteries
Durable period (Service life)	Blood Pressure Monitor (main unit): 10 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	175x91.5x53.5 ±1.0 mm

Weight	**PX7 Premium:** approximately 288 ±10 g (not including batteries) **Arm cuff:** approximately 170 g
Accessories:	- Prolife standard cuff 22–32 cm; - Prolife standard cuff 22–42 cm; - Prolife conic cuff 22–42 cm; - Prolife conic cuff 22–45 cm; - AC Adapter
Contents	- Blood Pressure Monitor; - Prolife conic cuff 22–45 cm; - 4 size AAA batteries (optional); - AC Adapter; - Prolife case; - Instruction manual; - Warranty card
Memory	1 x 199 memories for 1 users (SYS, DIA, Pulse)

Note

These specifications are subject to change without notice.

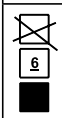
This Blood Pressure Monitor is clinically investigated according to the requirements of (AAMI/ESH/ISO) 2019 – (ISO 81060-2:2018) in the clinical validation study.

IP classification is degrees of protection provided by enclosures in accordance with IEC 60529.

Users can buy the AC Adapter in the market which must comply to EN60601-1, EN60601-1-2.

13 SYMBOLS DESCRIPTION

Symbols	Description	Symbols	Description
EC REP	Indicates the authorized representative in the European Community/ European Union		Applied part – Type BF. Degree of protection against electric shock (leakage current)

LOT	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified		Electrical and electronic equipment marks. Reduce electronic and electrical waste as unsorted waste and collect it separately
CE 0197	CE Marking of Conformity with indication of the identification number of the Notified Body		Refer to instruction manual / booklet
IP20	Ingress protection degree provided by IEC 60529		General warning sign
	Class II equipment. Protection against electric shock		Caution
	Date of manufacture		Keep dry
SN	Serial number		Manufacturer Indicates the medical device manufacturer
MD	Indicates the item is a medical device	UDI	Unique device identifier
	This is the correct upright position of the distribution packages for transport and / or storage		Cuff Connector
	Mobile Tips (option)		CUFF Tips (option)
	MAX Tips (option)		Fragile, handle with care
	Maximum number of identical transport packages / items which may be stacked on the bottom package, where "6" is the limiting number		Direct current

	Warning! Not suitable for children under 3 years old		Indicates the entity distributing the medical device into the locale
	Indicates the entity importing the medical device into the locale		

14 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		
This product is suitable for electromagnetic environment as described below. Users should ensure that they are used in such an environment		
Emission Test	**Compliance**	**Electromagnetic environment**
RF emission CISPR 11	Group 1	All models use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	All models are suitable for used in all 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	Compliance	
Voltage fluctuations/ flicker IEC 61000-3-3	Compliance	

Electromagnetic immunity: (IEC 60601-1-2)

Guidance & Declaration — electromagnetic immunity			
This product is suitable for the following electromagnetic environment. Users should ensure that they are 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 %
Electric fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (95 % dip in UT) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the all models require continued operation during power mains interruptions, it is recommended that the all models be powered from an uninterruptible power supply or a batter
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	N/A

NOTE: UT – is the a.c. mains voltage prior to application of the test level.

Guidance & Declaration - Electromagnetic immunity			
This product is suitable for use in the electromagnetic environment specified below. Users should ensure 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	N/A	Portable and mobile RF communications equipment should be used no closer to any part of all models, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	6 Vrms in ISM and amateur radio bands 10 V/m, 80 MHz to 2.7 GHz 385 MHz – 5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	N/A 10 V/m, 80 MHz to 2.7 GHz 385 MHz – 5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	Recommend separation distance: d=[3,5/V1]×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 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 meters (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 broadcast 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 models are used exceeds the applicable RF compliance level above, the model Air Mi 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models.

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

Recommended separation distances between portable and mobile RF communications equipment and all models			
This product is suitable for controlling the electromagnetic environment of radiofrequency interference. Users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters)			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d=1.2√P	**80 MHz to 800 MHz d=1.2√P**	**800 MHz to 2.5 GHz d=2.3√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 meters (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) accordable to the transmitter manufacturer.

NOTE 1: at 80 MHz and 800 MHz, 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.

prolife