

Introduction

Blood pressure measurements determined with X5 BT are equivalent to those obtained by a trained observer using cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers. This unit is to be used by adult consumers in a home environment. The patient is an intended operator. Do not use this device on infants or neonates. X5 BT is protected against manufacturing defects by an established International Warranty Program. For warranty information, you can contact the manufacturer, GMC Inc.

Attention: Consult the accompanying documents. Please read this manual carefully before use. For specific information on your own blood pressure, contact your physician. Please be sure to keep this manual.

PARR(Pulse Arrhythmia) Technology

Pulse Arrhythmia (PARR) technology specifically detects the existence of pulse arrhythmia, including atrial fibrillation (AFib), Atrial and / or Ventricular Premature Contractions (PC). Pulse Arrhythmia may be related to cardiac disorders, needs medical attention and thus early diagnosis is of paramount importance. The PARR technology detects arrhythmia during regular blood pressure checks without any additional user skills, user interaction and measurement prolongation. Beside the blood pressure diagnosis a specific pulse arrhythmia diagnosis is provided with PARR.

Note: The PARR detection of AFib and PC is provided with a clinically proven high detection probability [1]. However, the sensitivity and specificity is limited, thus most, but not all pulse arrhythmia will be detected and displayed. In certain patients with uncommon clinical conditions the PARR technology may not be able to detect pulse arrhythmia. This partly comes from the fact that some arrhythmia can only be found with an ECG diagnosis, but not with a pulse diagnosis. Thus PARR is not meant to replace any medical ECG diagnosis by your doctor. PARR provides an early detection of certain pulse arrhythmia, which inevitably need to be presented to your doctor in charge.

Remark: [1] Clinical Investigation of PARR - A new Oscillometric Pulse Arrhythmia Type Discriminating Detection Technology.

Atrial Fibrillation Detection (AFib)

The upper chambers of the heart (the atria) do not contract, but quiver and thus blood is driven irregularly and with lower efficiency into the ventricles. Subsequently irregular heartbeats occurs, which mostly are associated with a fast, yet highly instable heart rate. This condition is associated with a higher risk for the formation of cardiac blood clots. Amongst others, they may elevate the risk of brain strokes. Beside this atrial fibrillation may contribute to the severity of a chronic or acute heart failure condition and may be associated with other heart-related complications. Age dependent, about 10 %- 20 % percent of patients who suffer from an ischemic stroke also suffer from atrial fibrillation.

Atrial fibrillation most often initially occurs with temporary periods of arrhythmia and may progress to a permanent state of this disorder in the course of time. No matter, whether you intent to safeguard yourself from an undetected AFib state, or you measure during an ongoing period of active atrial fibrillation, or you measure in between periods of AFib, the PARR technology can be applied at any of these conditions. This unit is able to detect Atrial fibrillation (AFib). The ARR and AFib icons (♥AFib) are displayed right after the measurement if Atrial Fibrillation was detected.

Note: It is strongly recommended, that you consult your physician, if either the AFib icon occurs newly for several times, or, if your AFib is known to your doctor, but the incidence of AFib readings changes over time. Your doctor will then be able to provide all required medical test and possible therapeutic procedures.

Note: The presence of a cardiac pacemaker may impair the AFib detection by PARR.

Premature Contraction Detection (PC)

Extra abnormal heartbeats generated in irregular excitation sites of your heart, either in the atria (PAC), the ventricle (PVC) or the cardiac conduction nodes (PNC). These extra beats may disrupt your regular rhythm, they may come in early or cause a significant pauses regarding your perceivable pulse. This is called palpitations, which can be felt in your chest. They may occur as isolated, single events, as a series of irregular pulses or can be distributed all over your pulse beats. If they are not related to mental stress, or acute demanding physical load, they may be a marker for a multitude of cardiac disorders. Some of these disorders go along with an elevated risk profile for ischemic events, either in the heart (e.g. coronary heart disease) or outside the heart, e.g. an elevated risk for a stroke. Some PCs may indicate on valvular or myocardial disorders and become very important if a myocarditis (infection of the heart muscle) is suspected. This unit is able to detect premature contractions. The ARR and PC icons (♥PC) are displayed right after the measurement if premature contractions have been detected.

Note: It is strongly recommended, that you consult your physician, if either the PC icon occurs newly for several times, or, if your PC is known to your doctor, but the incidence of PC readings changes over time. Your doctor will then be able to provide all required medical test and possible therapeutic procedures.

Pulse Arrhythmia Detection (ARR)

Once the occurrence of pulse arrhythmia has been detected in the course of your blood pressure measurement, the icon ARR is displayed. In the case, that the found pulse arrhythmia can be specified by the PARR technology, the ARR icon is accompanied by the specifically detected type of arrhythmia, e.g. PC or AFib. Once the kind of found pulse arrhythmia cannot be safely determined by PARR, the device is displaying ARR without any additional pulse arrhythmia type icon.

Note: It is strongly recommended, that you consult your physician, if either the ARR icon occurs newly for several times, or, if your ARR is known to your doctor, but the incidence of ARR readings changes over time. This is independent whether the ARR icon is specified by another pulse arrhythmia icon or not. Your doctor will then be able to provide all required medical test and possible therapeutic procedures.

The PARR technology is able to detect and display combined pulse arrhythmia findings.

Display	Results
-	Normal finding
ARR	Pulse Arrhythmia without type-specific detection
ARR PC	Pulse Arrhythmia-Premature ventricular, atrial or nodal beat detection
ARR AFib	Pulse Arrhythmia-Atrial fibrillation detection
ARR AFib PC	Combined Pulse Arrhythmia: Atrial fibrillation & Premature beats detection

Real Fuzzy Measuring Technology

This unit uses the oscillometric method to detect your blood pressure. Before the cuff starts inflating, the device will establish a baseline cuff pressure equivalent to the air pressure. This unit will automatically determine the appropriate inflation level based on pressure oscillations, followed by cuff deflation.

During the deflation, the device will detect the amplitude and slope of the pressure oscillations and thereby determine your actual the systolic blood pressure, diastolic blood pressure, and pulse rate.

Preliminary Remarks

This Blood Pressure Monitor complies with the European regulations and bears the CE mark "CE 1639". The quality of the device has been verified and conforms to the provisions of the EC council directive 93/42/EEC (Medical Device Directive), Annex I essential requirements and applied harmonized standards.

EN 1060-1: 1995/A2: 2009 Non-invasive sphygmomanometers - Part 1 - General requirements

EN 1060-3: 1997/A2: 2009 Non -invasive sphygmomanometers - Part 3 - Supplementary requirements for electro-mechanical blood pressure measuring systems

EN 1060-4: 2004 Non-invasive sphygmomanometers - Part 4: Test Procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

ISO 81060-2: 2013 Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type.

This blood pressure monitor was designed for long service periods. In order to ensure continued accuracy, it's recommended that all digital blood pressure monitors require re-calibration. This monitor (under normal usage with approx. 3 measurements a day) does not require re-calibration for 2 years. Once the unit should be re-calibrated the device will display **ER**. The unit should also be re-calibrated if the monitor sustains damage due to blunt force (such as dropping) or exposure to fluids and / or extreme hot or cold temperature / humidity changes. When **ER** appears, simply return your device to your nearest dealer for re-calibration service.

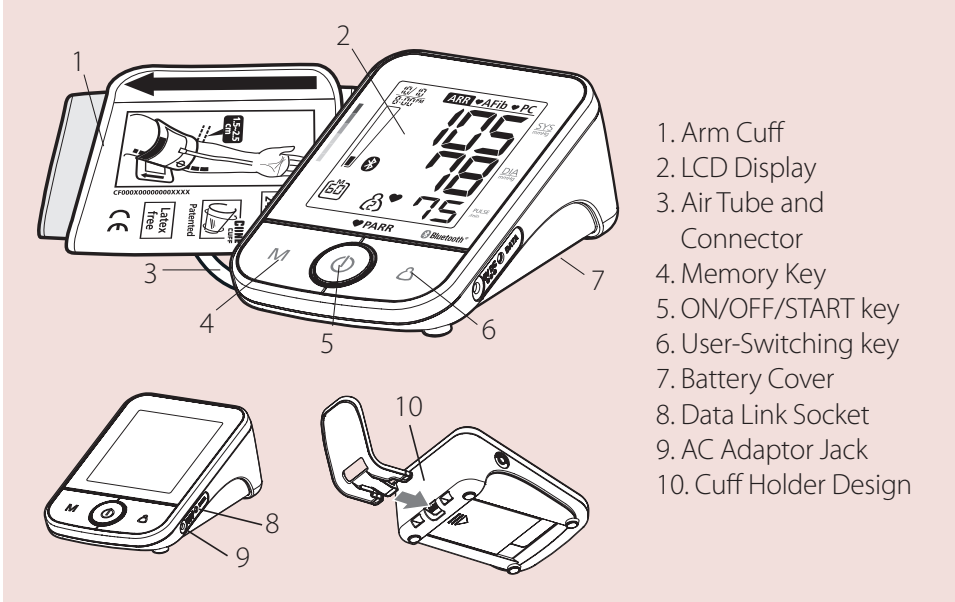
Blood Pressure Standard

Refer to the definitions of the World Health Organization, the blood pressure ranges can be classified into 6 grades. (Ref. 1999 WHO-International Society of Hypertension Guidelines for the management of Hypertension). This blood pressure classification are based on statistical data, and may not be directly applicable to any particular patient. It is important that you consult with your physician regularly. Your physician will tell you your normal blood pressure range as well as the point at which you will be considered at risk. For reliable monitoring and reference of your blood pressure, keeping long-term records is recommended.

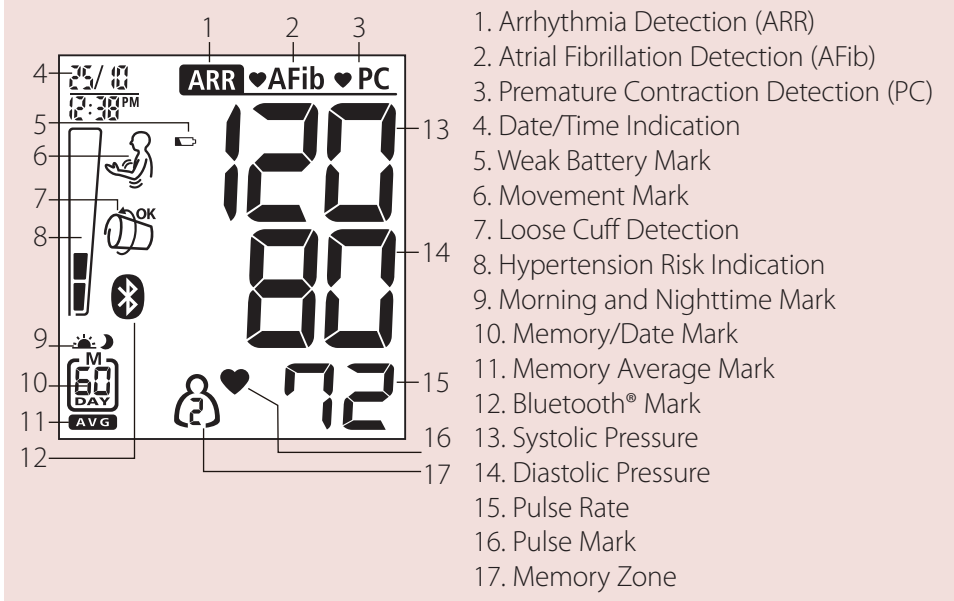
Blood Pressure Standard World Health Organization (WHO) : 1999

	Systolic Pressure (mmHg)	Diastolic Pressure (mmHg)
Optimal	<120	and <80
Normal	120~129	or 80~84
High-normal	130~139	or 85~89
Grade 1 hypertension (mild)	140~159	or 90~99
Grade 2 hypertension (moderate)	160~179	or 100~109
Grade 3 hypertension	≥180	or ≥110

Name/Function of Each Part



Name/Function of Each Part



Loose Cuff Detection

If the cuff was applied too loosely, it may cause unreliable measurement results or measurements can fail to start. The "Loose Cuff Detection" can help to determine if the cuff is wrapped snugly enough. The specified icon appears once a "loosen cuff" has been detected during measurement. Otherwise the specified icon appears if the cuff is wrapped correctly during measurement.

Movement Detection

The "Movement Detection" helps reminding the user to remain still and is indicating any adverse body movement during measurement. The specified icon appears once a "body movement" has been detected during and after such a measurement.

Note: It's highly recommended that you measure again if the icon appears.

Guest Mode

This monitor has a non-stored single measurement function. Press the User-Switching key to select the memory zone of guest , and follow the Measurement Procedure to take a measurement correctly. When the measurement is completed, the measurement value will not be stored in memory zone.

Hypertension Risk Indication (HRI)

The World Health Organization, classifying blood pressure ranges into 6 grades. This unit is equipped with an innovative blood pressure risk indication, which visually indicates the assumed risk level (optimal / normal / high-normal/ grade1 hypertension / grade 2 hypertension / grade 3 hypertension) of your result, making the meaning of your findings comprehensive.

Error Codes for your reference

EE / Measurement Error: Make sure the L-plug is securely connected to the air socket and calmly measure again. Wrap the cuff correctly around your arm and keep arm steady during measurement. If the error keeps occurring, return the device to your local distributor or service centre.

E1 / Air Circuit Abnormality: Make sure the L-Plug is securely connected to the air socket on the side of the unit and calmly measure again. If the errors still occur, return the device to your local distributor or service centre for help.

E2 / Pressure Exceeding 300 mmHg: Switch the unit off and measure again quietly. If the error keeps occurring, return the device to your local distributor or service centre.

E3 / Data Error: Remove the batteries, wait for 60 seconds, and reload. If the error keeps occurring, return the device to your local distributor or service centre.

Er / Exceeding Measurement Range: Measure again quietly. If the error keeps occurring, return the device to your local distributor or service centre.

Using the AC Adaptor (Optional)

- 1.Connect the AC adaptor with the AC adaptor jack on the right side of the unit.
- 2.Plug the AC adaptor into the socket. (AC adaptors with required voltage and current indicated near the AC adaptor jack.)

Caution:

1. Please unload the batteries when operating with the AC mode for a longer period of time . Leaving the batteries in the compartment for a long time may cause leakage, which may lead to damage of the unit.
2. No batteries are needed when operating with the AC mode.
3. AC adaptors are optional. Please contact the distributor for the compatible AC adaptors.
4. Use only the authorized AC Adaptor with this blood pressure monitor. Information for the authorized AC adaptor, please refer to APPENDIX 1.

Installing Batteries

1. Press down and lift the battery cover in the direction of the arrow to open the battery compartment.
2. Install or replace 4 "AAA" sized batteries in the battery compartment according to the indications inside the compartment.
3. Replace the battery cover by clicking in the bottom hooks first, then push in the top end of the battery cover.

4. Replace the batteries in pairs. Remove batteries when unit is not in use for extended periods of time.

You need to replace the batteries when

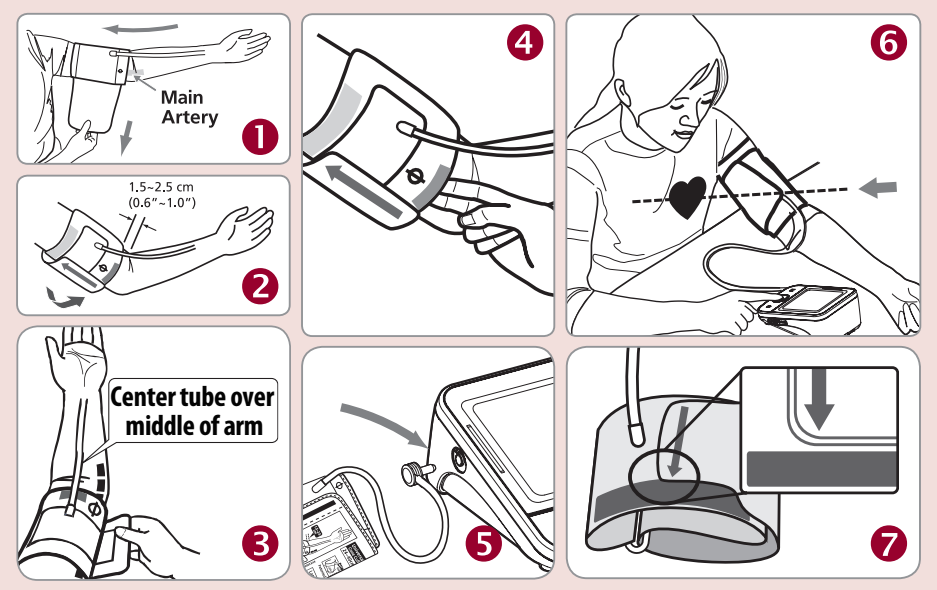
1. Low battery icon appears on display.
2. The ON/OFF/START key is pressed and nothing appears on display.

Caution:

1. Batteries are hazardous waste. Do not dispose them together with the household garbage.
2. There are no user serviceable parts inside. Batteries or damage from old batteries are not covered by warranty.
3. Use exclusively brand batteries. Always replace with new batteries together. Use batteries of the same brand and same type.

Applying the Cuff

1. Unwrap the arm cuff, leaving the end of the cuff through the D-ring of the cuff.
2. Put your left arm through the cuff loop. The color strip indication should be positioned closer to you with the tube pointing in the direction of your arm (Fig. ①). Turn your left palm upward and place the edge of the arm cuff at approximately 1.5 to 2.5 cm above the inner side of the elbow joint (Fig. ②). Tighten the cuff by pulling the end of the cuff.
3. Center the tube over the middle of the arm. Press the hook and loop material together securely. Allow room for 2 fingers to fit between the cuff and your arm. Position the artery mark (②) over the main artery (on the inside of your arm) (Fig. ③,④). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.
4. Plug in the cuff connecting tube into the unit (Fig. ⑤).
5. Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked (Fig. ⑥).
6. This cuff is suitable for your use if the arrow falls within the solid color line as shown on the right (Fig. ⑦). If the arrow falls outside the solid color line, you will need a cuff with other circumstances. Contact your local dealer for additional size cuffs.



Measurement Procedures

Here are a few helpful tips to help you obtain more accurate readings:

- Blood pressure changes with every heartbeat and is in constant fluctuation throughout the day.
- Blood pressure recording can be affected by the position of the user, his or her physiological condition and other factors. For greatest accuracy, wait one hour after exercising, bathing, eating, drinking beverages with alcohol or caffeine, or smoking to measure blood pressure.
- Before measurement, it's suggested that you sit quietly for at least 5 minutes as measurement taken during a relaxed state will have greater accuracy. You should not be physically tired or exhausted while taking a measurement.
- Do not take measurements if you are under stress or tension.
- Sit upright in a chair, and take 5-6 deep breaths. Avoid leaning back while the measurement is being taken.
- Do not cross the legs while sitting and keep the feet flat on the floor during measurement.
- During measurement, do not talk or move your arm or hand muscles.
- Take your blood pressure at normal body temperature. If you are feeling cold or hot, wait a while before taking a measurement.
- If the monitor is stored at very low temperature (near freezing), have it placed at a warm location for at least one hour before using it.
- Wait 5 minutes before taking the next measurement.
- 1. Press the User-Switching key to select memory zone 1, memory zone 2 or guest mode. After a memory zone is selected, press the ON/OFF/START key to reset the monitor so it can start measurement in the chosen memory zone.
- 2. Press the ON/OFF/START key. All digits will light up, checking the display functions. The checking procedure will be completed in 2 seconds.
- 3. After all symbols appear, the display will show a blinking "0". The monitor is ready to measure and will automatically inflate the cuff slowly to start measurement.
- 4. When the measurement is completed, the cuff will exhaust the pressure inside. Systolic pressure, diastolic pressure and pulse will be shown simultaneously on the LCD screen. The measurement is then automatically stored into the pre-designated memory zone.
- 5. In order to enhance the probability of pulse arrhythmia detection by the PARR technology, measurement repetitions are recommended.