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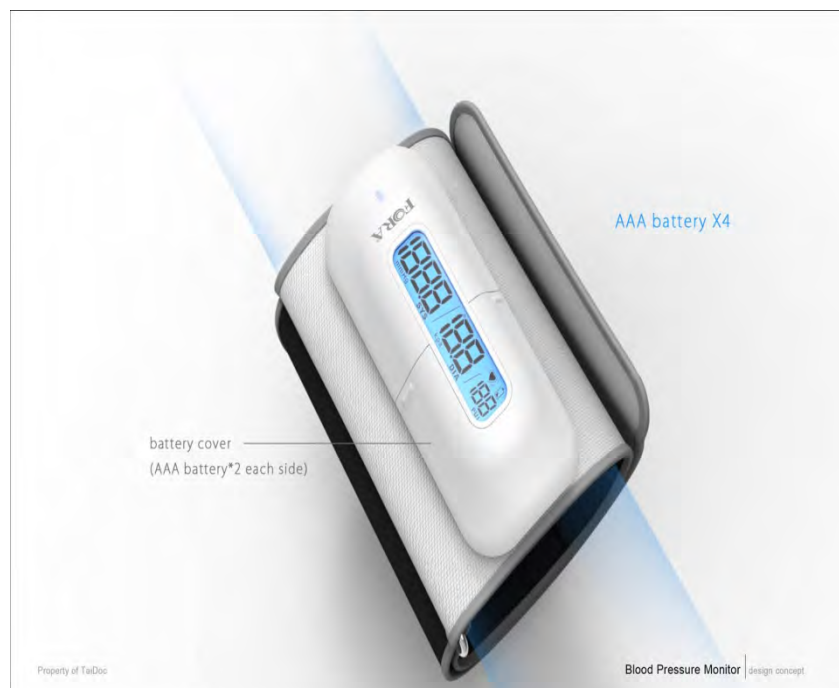
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Fora Care

Blood Pressure Monitoring System

Model number: P80



Owner's Manual

Version 1.0

2013-06



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Dear FORA Blood Pressure Monitoring System Owner:

Thank you for purchasing the **FORA Blood Pressure Monitoring System**. This manual provides important information to help you operate this system correctly. Before using this product, please read the following contents thoroughly and carefully.

With the compact size and easy operation of this system, you can easily monitor your blood pressure by yourself at any time or place. In addition, this system can help you and your healthcare professionals to monitor and adjust your treatment plans, and keep your blood pressure under control.

If you have other questions regarding this product, please contact the place of purchase.



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IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use the device if it is not working properly or damaged.
3. Do **NOT** use the equipment where aerosol sprays are being used, or where oxygen is being administered.
4. Do **NOT** use under any circumstances on newborns.
5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your doctor to have the results interpreted.
6. Keep the equipment away from hot surfaces.
7. Do **NOT** apply the cuff to areas other than the place directed.
8. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
9. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE



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BEFORE YOU BEGIN

Intended Use

FORA Blood Pressure Monitoring System is a system designed to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. It is intended for individuals age 18 and above use at home and in clinical settings. The device is not to be used for the diagnosis of hypertension or for testing on newborns.

Test Principle

Blood pressure is measured non-invasively at the arm based on oscillometric method.

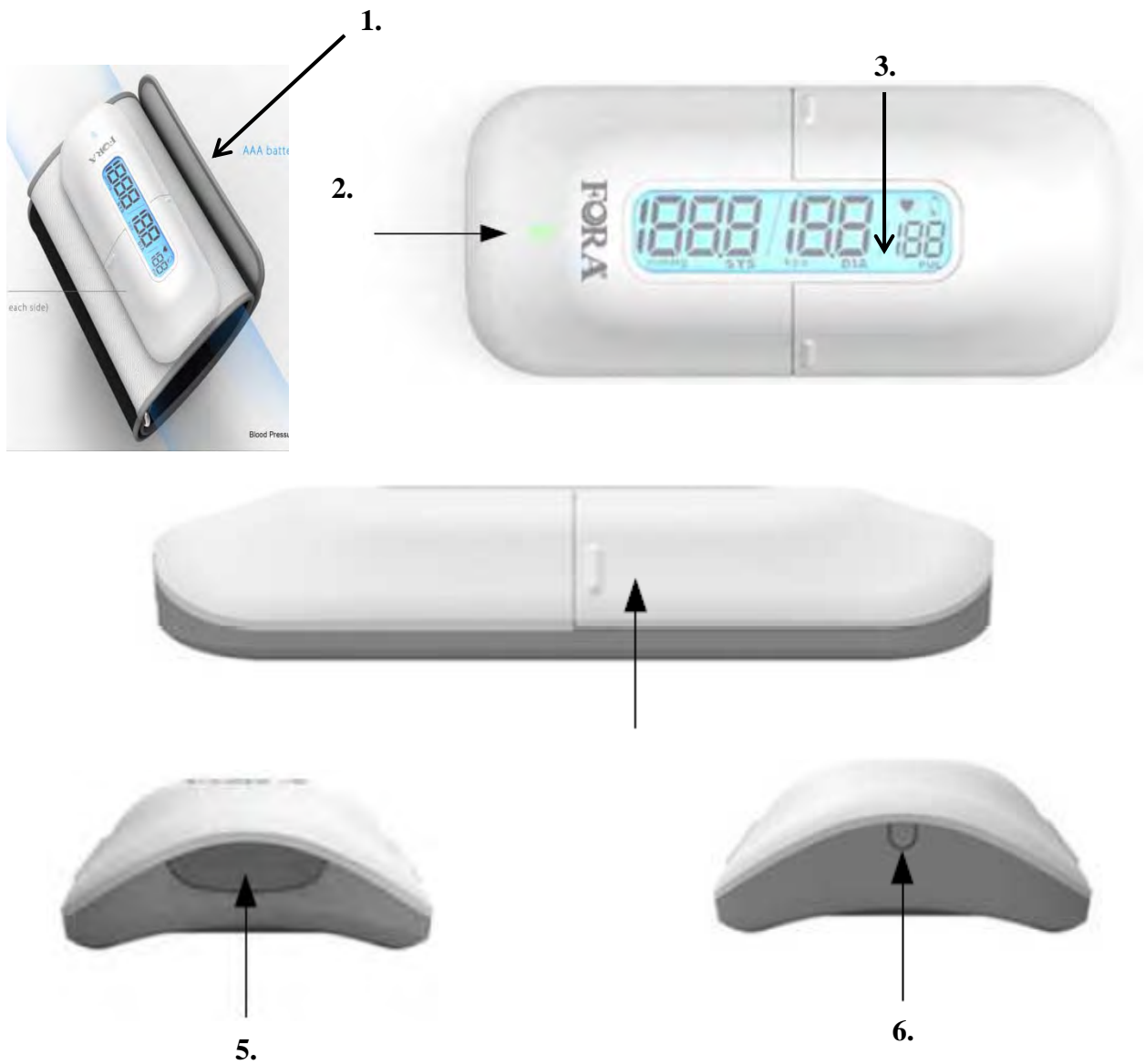
This device is **NOT** able to take measurements in the presence of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation. It may produce reading error.

Contents of System

Your new **FORA Blood Pressure Monitoring System** includes:

- (1) Meter with cuff
- (2) Owner's manual
- (3) Warranty card
- (4) 4 x AAA batteries
- (5) Protective Wallet

Meter Overview



1. CUFF

2. BT INDICATOR

Download test results with a Bluetooth connection.

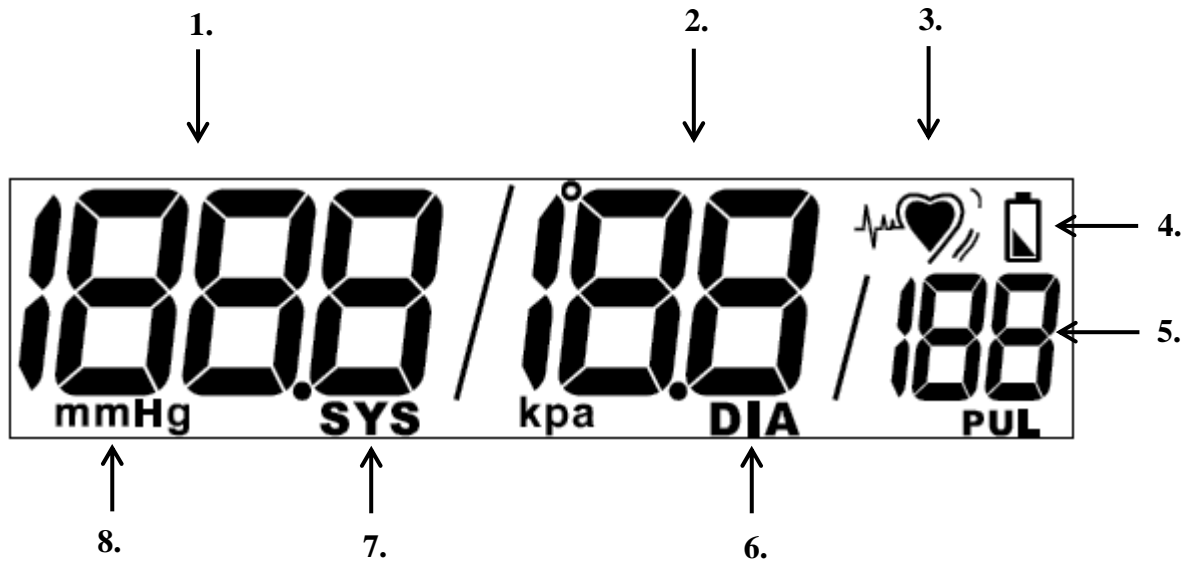
3. DISPLAY SCREEN

4. BATTERY COMPARTMENT

5. ON/OFF BUTTON

6. BT PAIRING BUTTON

Display Screen



1. Systolic Pressure Value
2. Diastolic Pressure Value
3. Pulse Rate Symbol
4. Low Battery Symbol

5. Pulse Rate
6. Diastolic Pressure Symbol
7. Systolic Pressure Symbol
8. Units of Blood Pressure

HOW TO INSTALL AND UPDATE THE TDLink BP



. You can use the device, FORA Blood Pressure Monitoring System, by itself or with the TDLink BP App. TDLink BP App is available on the App Store/Play Store for free download. You must be connected to the internet to download the App.

TDLink BP App is designed to assist you in easy blood pressure testing, recording, tracking and monitoring.

It is simple and intuitive to use, for better understanding of your current condition and to achieve better hypertension control.

System Requirement

iOS version 5.0.1 or higher.

Updating

When new features are added to the TDLink BP App, the App Store will notify you automatically. Please perform the updates accordingly to provide you with the latest features that we have developed in your best interest.

BLUETOOTH PAIRING

Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

NOTE:

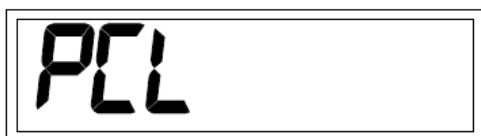
This step is recommended when the user needs to pair this meter to a Bluetooth receiver for the first time, or when user needs to pair this meter to another new Bluetooth receiver.

1. Installing the TDLink BP app

For more information, please refer to the section” HOW TO INSTALL AND UPDATE THE TDLink BP”.

2. Connecting blood pressure meter with your mobile device

- Turn on the Bluetooth on both your blood pressure meter and your mobile device (iOS with 5.0.1 or higher and Android with 2.3.3 or higher). “PCL” will appear on the meter display and the BT indicator will start to flash.



- Your mobile device will now begin searching for the Bluetooth signal to pair with.
- Once the mobile device has found the blood pressure meter; the name of the meter will appear on the pairing list. Please select and add to the list.
- On the mobile phone, the blood pressure meter will be shown as a paired device and on the blood pressure meter the Bluetooth Indicator LED will light solid, indicating that the devices have been successfully paired.

3. Data transmission

The data transmission will begin spontaneously right after the measurement when the Bluetooth is turn on.

Bluetooth indicator on the blood pressure meter:

Bluetooth Indicator	Status
Flash fast	The meter is searching the device of Bluetooth signal.
Flash slowly	The meter is pairing with the device of Bluetooth.
Lit solid	The meter is transmitting the data now the connection is established.

Mobile Phone Compatibility Issues

The Bluetooth functionality is implemented in different ways by the various mobile phone manufacturers. Unfortunately, in some mobile phone models, even with Bluetooth functionality, they may be compatible only with certain types of devices. If a problem occurs in the connection between your mobile phone and the blood pressure meter, or if you are uncertain regarding your mobile phone's Bluetooth capabilities, please consult your mobile phone manual or blood pressure meter manual or alternatively contact your local customer service for assistance.

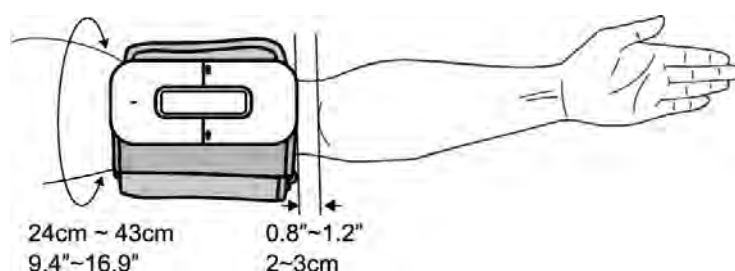
IMPORTANT INFORMATION ABOUT PERFORMING YOUR BLOOD PRESSURE TEST

Before Measurement

- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement.
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measurement.
- Do not measure when feeling anxious or tense.
- Take a 5-10 minute break between measurements. This break can be longer if necessary, depending on your physical condition
- Keep the records for your doctor as reference.
- Blood pressure naturally varies between each arm. Always measure your blood pressure on the same arm.

Apply the Cuff Properly

1. Stretch your left (right) arm in front of you with your palm facing up. Slide and place the cuff onto your arm, the arrow should point toward the upper arm.
2. Wrap and tighten the cuff above your elbow. The red line on the edge of the cuff should be approximately **0.8" to 1.2" (2 cm to 3 cm)** above your elbow.



3. Leave a little free space between the arm and the cuff; you should be able to fit two fingers between them. Clothing must not restrict the arm. Remove all clothing covering or constricting the measurement arm.

4. Press the hook material firmly against the pile material. The top and bottom edges of the cuff should be tightened evenly around your upper arm.

Proper Measurement Position

1. Sit down for at least 10 minutes before measuring.

2. Place your elbow on a flat surface. Relax your hand with the palm facing up.

3. Make sure the cuff is about the same height as the location of your heart.



4. Press **ON/OFF Button**. Remain still and do not talk or move during the measurement.

WARNING:

► If the cuff is relatively lower (higher) than the heart, the obtained blood pressure value could be higher (lower) than the actual value. A 15 cm difference in height may result in an error around 10 mmHg.

5. Measurement is in progress.

After the meter is turned on, the cuff will begin to inflate automatically.

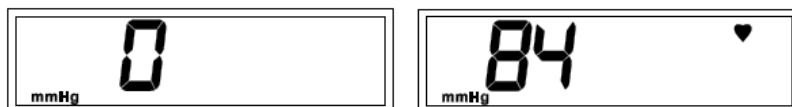
HOW TO TEST YOUR BLOOD PRESSURE

Taking Measurement by the Device Itself

Always apply the pressure cuff before turning on the meter.

1. Press **ON/OFF Button**. All the LCD symbols will appear with a long “beeping” sound. Then the cuff will begin to inflate automatically.

2. Pump starts to inflate and pressure in cuff increases to working pressure.



3. The heart symbol “♥” will show silently when pulse is detected during the deflation. When signal of pulse becomes strong, “♥” icon starts to flash.

4. After the measurement, the meter displays the systolic pressure, diastolic pressure and pulse rate.



5. Press **ON/OFF Button** to switch off. Or it will switch off automatically after being idle for 3 minutes.



NOTE

- If you press **ON/OFF Button** during measurement, the meter will be turned off.



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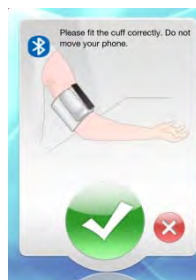
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Taking Measurement with the TDLink BP App

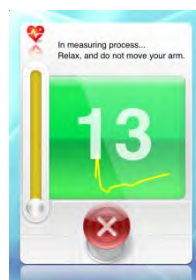
1. Turn on the Bluetooth switch on your mobile and connect with “**FORA Blood Pressure Monitoring System**” before doing the test.



2. Turn on TDLink BP App; always apply the pressure cuff before turning on the meter.



3. Press **ON/OFF Button**. All the LCD symbols will appear with a long “beeping” sound on the device monitor. Then the cuff will begin to inflate automatically until it reaches the working pressure.



4. Pulse rate is detected during the deflation.
5. After the measurement, the meter displays the systolic pressure, diastolic pressure and pulse rate.





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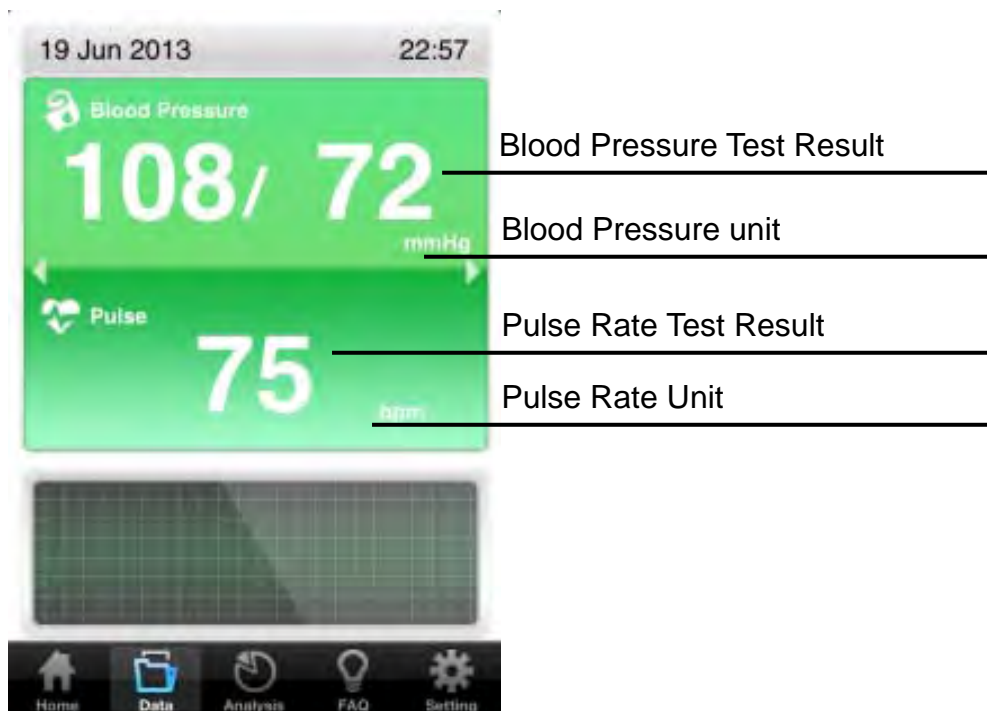
VIEWING PAST TEST RESULTS

Data

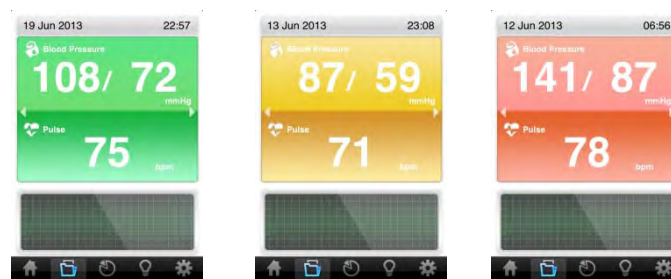
Reviewing Data Record

The meter stores the blood pressure test results along with respective dates and times in memory under the mobile device.

Data Record Screen



1. Press "Data" on the main menu bar to review the records. The first reading you see is the last blood pressure result.
2. Swipe left or right to recall the previous test results stored in the memory.



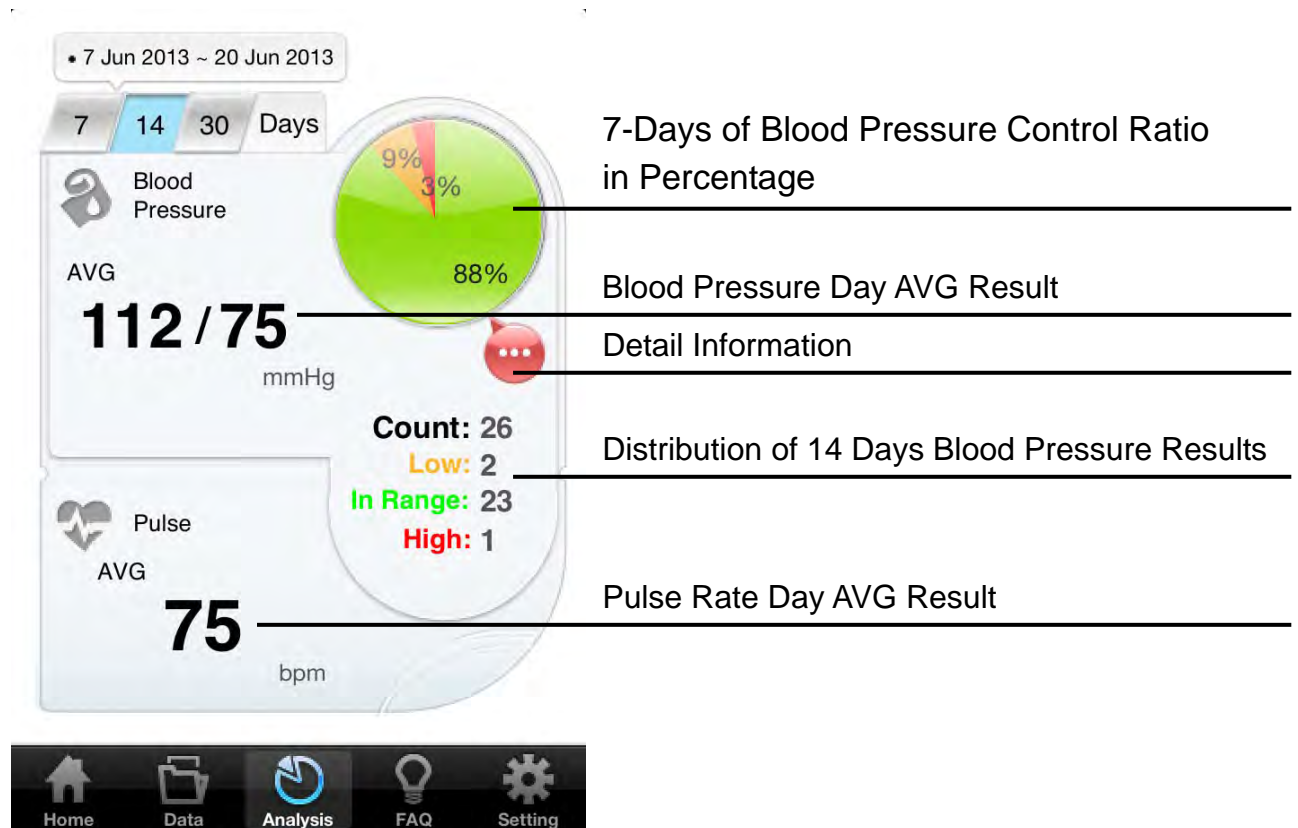
VIEWING PAST TEST RESULTS

Analysis

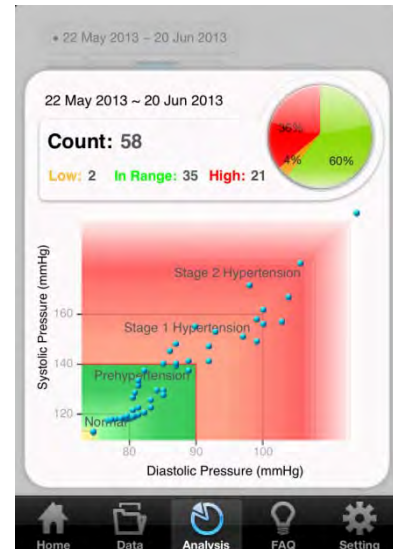
Reviewing Blood Pressure Day Average Results

The TDLink BP App offers you 7-, 14-, and 30- day average results and Pie Chart to assist you to monitoring your blood pressure.

Day Average Screen

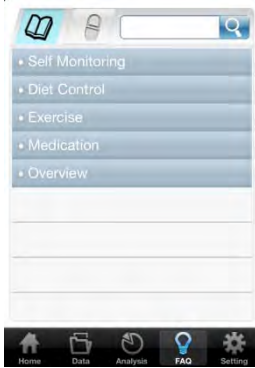


1. Press **"Analysis"** on the main menu bar to enter the Day AVG records.
2. You will see the current 7 Days of blood pressure control ratio in percentage and the distribution of all the results.
3. Click at Detail Information (red circle) to find out more information.
4. To quickly switch between, simply press "7", "14" and "30" icon on the top.



FAQ

1. Select the FAQ mode from the Main Menu Bar.



Select FAQ in the Main Menu Bar to enter, and then the Sub Menu will appear. You will see the information categorized into different sections, such as Self-Monitoring, Diet Control, Exercise, Medication and Overview.

If you wish to find the specific information much quicker, you can also search by typing key words in the search bar on the top of each section page.


MAINTENANCE

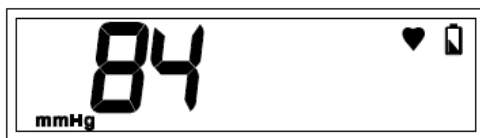
Battery

Your meter comes with four (4)1.5V AAA size alkaline batteries.

☉ Low Battery Signal

The meter will display either of the two messages below to alert you when the meter power is getting low.

1. The  symbol appears along with display messages: The meter is functional and the result remains accurate, but it is time to change the batteries.



2. The  symbol appears with E-b:

The power is not enough to do a test. You must change the batteries immediately.



◎ Replacing the Battery

To replace the batteries, make sure the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with four 1.5V AAA size alkaline batteries.
3. Close the battery cover.

NOTE:

- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

To avoid the meter attracting dirt, dust or other contaminants, wash and dry your hands thoroughly before use.

◎ Cleaning

- To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT flush with water.
- Do NOT use organic solvents to clean the meter.
- Do NOT wash the pressure cuff.
- Do NOT iron the pressure cuff.

◎ Meter Storage

- Storage condition: -25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping or heavy impact.
- Avoid direct sunlight and high humidity.

DETAILED INFORMATION

◎ Reference Values

Clinical studies show that adult diabetes is often accompanied by elevated blood pressure. People with diabetes can reduce their heart risk by managing their blood pressure along with diabetes treatment^{*4}.

Monitoring your routine blood pressure trend helps you to know your body condition. Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include obesity, lack of exercise and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction. The recommended blood pressure range is as below:

Classification	Systolic Pressure (mmHg)	Diastolic Pressure (mmHg)
Hypotension ^{*2}	Less than 90	Less than 60
Normal ^{*3}	Less than 120	Less than 80
Pre-hypertension ^{*3}	120 – 139	80 – 89
Stage 1 Hypertension ^{*3}	140 – 159	90 – 99
Stage 2 Hypertension ^{*3}	160 or more	100 or more

^{*2}: National Heart, Lung, and Blood Institute, Diseases and Conditions

^{*3}: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication. 2003. No. 03-5233



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*⁴: American Diabetes Association: The Diabetes-Heart Disease Link Surveying Attitudes,



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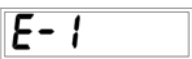
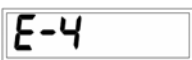



SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair by yourself and never try to disassemble the meter under any circumstances.

Result Readings of App

MESSAGE	WHAT IT MEANS
	Reading in yellow when blood pressure is low.
	Reading in green when blood pressure is normal.
	Reading in red when blood pressure is high.

Error Messages of Meter

MESSAGE	CAUSE	WHAT TO DO
	Inflation or pressure error	Please contact local customer service for help.
	Blood pressure measurement error.	Refit cuff tightly and correctly. Relax and repeat the measurement. If error still remains, contact local customer service for help.
	Problems with the meter.	Review the instructions and repeat the test. If the meter still does not work, please contact the local customer service for help.
		
	Battery is too low.	Repeat with new batteries.

Troubleshooting

1. If no display appears after pressing **ON/OFF Button**:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Batteries incorrectly installed or absent.	Check that the batteries are correctly installed.

2. If the heart rate is higher/lower than user's average:

POSSIBLE CAUSE	WHAT TO DO
Movement during measurement.	Repeat measurement.
Measurement taken just after exercise.	Rest at least 30 minutes before repeating measurement.

3. If the result is higher/lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
May not be in correct position while measuring.	Adjust to the correct position to measure.
Blood pressure naturally varies from time to time.	Keep in mind for next measurement.

4. If the cuff inflates again while measuring:

POSSIBLE CAUSE	WHAT TO DO
Cuff is not fastened.	Fasten the cuff again.
If user's blood pressure is higher than the pressure the device has inflated, the device will automatically increase the pressure and start to inflate again. Stay relaxed and wait for the measurement.	



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SPECIFICATIONS

■ System performance

Power source:	Four 1.5V AAA alkaline batteries
Size of meter w/o cuff:	145 (L) x 64.5 (W) x 29.6 (H)mm, 240g without batteries.
Power saving:	Automatic power off if system idle for 3 minutes.
System operating condition:	5°C to 40°C (41°F to 104°F), 15% to 93% RH, 700 hPa to 1060 hPa
Meter storage condition:	-25°C to 70°C (-13°F to 158°F), 10% to 95% RH
Waterproof grade	IP22
The expected service life	2 years

■ Blood pressure measurement performance

Pressure range:	0 - 300 mmHg
Heart rate range:	40 - 199 beat per minute
Systolic Measurement Range:	50 mmHg -250 mmHg
Diastolic Measurement Range:	30 mmHg -180 mmHg
Pulse Rate Measurement Range:	40 -199 beats / minute
Maximum inflation pressure:	280 mmHg
Accuracy of Pressure:	±3 mmHg or ±2% of reading
Accuracy of Pulse rate:	±4% of reading
Measurement unit:	mmHg

This device has been tested to meet the electrical and safety requirements of: IEC 60601-1, and IEC 60601-1-2

Reference to Standards:

- IEC60601-1 General requirement for safety
- IEC60601-1-2 Requirements for EMC

IP22:

- Object size protected against: >12.5 mm (Fingers or similar objects)
- Protected against: Dripping water when tilted up to 15°



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FEDERAL COMMUNICATIONS COMMISSION (FCC) STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference and
- 2) This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific



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operating instructions for satisfying RF exposure compliance.

Distributed by:

Fora Care Inc.

893 Patriot Dr., Suite D
Moorpark, CA 93021 U.S.A.

Toll Free: 1-866-469-2632

Hours of Operation: 24 hours, 7 days/week