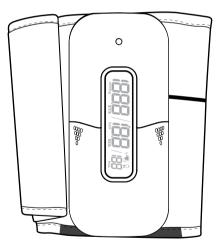
TD-3140 Blood Pressure Monitor

Owner's Manual



Dear TD-3140 System Owner:

Thank you for choosing **TD-3140** 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.

Managing your blood pressure is simple with this device. It's small enough to take with you anywhere, and auto-uploads all of your readings to the **MbH BP** smartphone App. In addition, this device will help you and your healthcare professional, to keep your blood pressure under control and adjust your treatments plans as needed.

If you have further questions about this system, please contact the Customer Service for assistance.

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IMPORTANT SAFETY INSTRUCTIONS READ BEFORE USE

The following basic safety precautions should always be taken.

- 1. Use the 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 under any circumstances on newborns.
- 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.
- 5. Keep the equipment away from hot surfaces.
- 6. Do **NOT** apply the cuff to areas other than the place directed.
- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges. This may cause erroneous results.
- 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

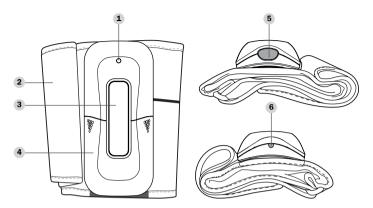
TD-3140 Blood Pressure Monitoring System is a system designed to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. It is intended for individuals age 18 and up, for use in a home or clinical setting. 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.

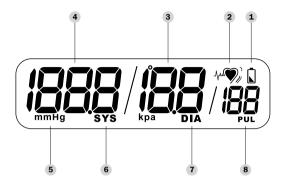
This device is **NOT** able to take measurements in the presence of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation. It may produce reading error.

Meter Overview



- Bluetooth Indicator
 Download test results with a Bluetooth connection.
- 2 Cuff (immovable)
- 3 Display Screen
- 4 Battery Compartment
- 5 ON/OFF Button
- 6 Bluetooth Pairing Button

Display Screen



- 1 Low Battery Symbol
- 2 Pulse Rate Symbol
- 3 Diastolic Pressure Value
- Systolic Pressure Value
- 5 Units of Blood Pressure
- 6 Systolic Pressure Symbol
- **7** Diastolic Pressure Symbol
- 8 Pulse Rate

HOW TO INSTALL AND UPDATE THE MbH BP BLOOD PRESSURE MANAGER



You can use the **TD-3140** Blood Pressure Monitoring System by itself or with the **MbH BP** Blood Pressure Manager App. **MbH BP** Blood Pressure Manager is designed to assist you in easily monitoring, recording, and tracking your blood pressure. The app is simple to use and helps you to better understand your current condition as well as to better control your hypertension.

System Requirement

For the requirement of OS version, please find on App Store or Google Play when you download the app

Installing

MbH BP Blood Pressure Manager is available on the App Store/Play Store for free download. Connect your mobile device to the internet to download the **MbH BP** Blood Pressure Manager and then install on your mobile device.

Updating

When new features are added to the **MbH BP** Blood Pressure Manager, 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

You can transmit your data from the meter to your devices via Bluetooth. Please contact your local customer service or place of purchase for assistance. Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data. Please refer to the images on the quick start guide for detailed procedures.

Pairing with your mobile device

- 1. Turn on the **Bluetooth** function on your mobile device.
- 2. Press the **Bluetooth button** on the meter. "PCL" will be displayed on the meter screen.
- **3.** Follow the instruction on your app to pair the device. (Ex. Scan to find the meter and then add it into the app.)
- After successfully pairing the app with the device, the Bluetooth function of meter shall be on before transmitting the data to your app.

Bluetooth indicator on the meter

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

NOTE:

- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device supporting Bluetooth Smart Technology has turned on Bluetooth before transmitting the data and the meter is within the receiving range. For the requirement of OS version, please find on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers, the compatibility issue between your mobile device and the meter may occur.

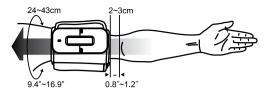
IMPORTANT INFORMATION ABOUT PERFORMING A BLOOD PRESSURE TEST

Before Measurement

- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement.
- Wait for 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

- 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 forearm.
- 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.



 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.

NOTE:

The blood pressure monitor is fixed onto the cuff. Do NOT remove the cuff or change to other different sized cuff.

Proper Measurement Position



- **1.** Sit or lie down for at least 10 minutes before measuring.
- Place your elbow on a flat surface. Relax your hand with the palm facing up.
- **3.** 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 (5.9") difference in height may result in an error around 10 mmHg.

<u>HOW TO TEST YOUR BLOOD</u> PRESSURE

Taking Measurement with the Device Itself Always apply the pressure cuff before turning on the meter.

1. Tap 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. The pressure in cuff increases to working pressure.
- The heart symbol "♥" will show silently when pulse is detected during the measurement. 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.
- Tap ON/OFF Button to switch off. The meter will switch off automatically after being idle for 3 minutes.

NOTE:

 When the "Syn" icon appears on the screen, it indicates you have not paired the meter to your mobile device. You need to synchronize



with your mobile device in order to adjust the date and time settings, or the measured result will be stored in the meter's memory with incorrect date and time.

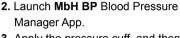
• If you tap ON/OFF Button during measurement, the meter will be turned off.

Taking Measurement with the TAIDOC TD3140 App

All the screenshots displayed below come from the display screen of the Bluetooth receiver installed with **MbH BP** Blood Pressure Manager App, not from the display screen of the meter.

Single Measurement

1. Turn on the Bluetooth switch on your mobile device before doing the test.



 Apply the pressure cuff, and then tap
 (in green) on the screen of MbH BP Blood Pressure Manager App. All the LCD symbols will appear with a long "beeping" sound on the device monitor. The cuff will begin to inflate automatically until it reaches the working pressure.

The " ♥ " (in green) will turn into " ♥ " (in red) on the App screen during measurement. If you want to stop the measurement, press " ♥ " (in red) to terminate it, and the meter will be switched off.

NOTE:

If the connection is established, the meter will enter PCL mode.

4. The pulse rate is detected during the measurement.





5. After the measurement, the app screen displays the systolic pressure, diastolic pressure and pulse rate. If the measurement is initiated via the app, you will also see a curve diagram below the pulse rate. The diagram is only available when the measurement is initiated via the app rather than by the meter's ON/OFF button. Tap on the diagram to view more information. This curve and its contents are for reference only. Please seek medical professionals for further diagnoses.

Average Measurement

This function automatically performs three (3) consecutive blood pressure measurements and displays the average result in the end. This function is only available when your meter is connected to your mobile device.



- Press the Bluetooth button. The "PCL" icon will appear on the meter display, indicating that the device is ready to transmit data.
- 2. Launch MbH BP Blood Pressure Manager App.
- Set Average Mode to ON and tap " (in green) on the screen of MbH BP Blood Pressure Manager App. Then the cuff will begin to inflate automatically.

The " " (in green) will turn into " " (in red) on the App screen during measurement. If you want to stop the measurement, press " " (in red) to terminate it, and the meter will be switched off.

After the first measurement is complete, the device and MbH
 BP Blood Pressure Manager app will start counting down before the second measurement begins. The device will take three (3) measurements consecutively with an interval of 20 seconds.

NOTE:

When the difference between the first and second systolic pressure is more than 15 mmHg, the time interval for the third measurement will be 40 seconds.

5. After taking three measurements, the app screen displays the average result with an "**AVG**" tag.



6. Touch the waveform area under the pulse rate, a pop-up window will appear to display the predicted analysis of your average result. Press the upper-right icon "x" to close the pop-up window.

NOTE: Always apply the pressure cuff before turning on the meter.

MAINTENANCE

Battery

Your meter comes with four (4) 1.5 V 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.
- **3.** Replace with four 1.5 V AAA size alkaline batteries in accordance with the mark +/- indication in the battery compartment.
- 4. 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 the batteries according to your local environmental regulations.

 Replacing the batteries does not affect the test results stored in memory. After battery replacement, please pair the meter with your mobile device again to synchronize time and date, so measurements taken afterwards will be stored in memory with correct time and date.

Caring for your meter

To avoid the meter from 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 or 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^{*1}.

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	≤ 90	≤ 60
Normal*3	< 120	< 80
Pre-hypertension*3	120 – 139	80 - 89
Stage 1 Hypertension*3	140 – 159	90 – 99
Stage 2 Hypertension*3	≥ 160	≥ 100

- *1: American Diabetes Association: The Diabetes-Heart Disease Link Surveying Attitudes, Knowledge and Risk (2002).
- *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.

SYSTEM TROUBLESHOOTING

Error Messages on Meter

MESSAGE	PROBABLE CAUSE	SOLUTION
E-1	Inflation or pressure error.	Please contact local customer service for help.
E-4	Blood pressure measurement error.	Refit cuff tightly and correctly. Relax and repeat the measurement. If error still remains, contact local customer service for help.
E-A E-E	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.
E-b	Battery is too low.	Replace with new batteries.

NOTE:

The information here is only displayed on the meter screen.

Troubleshooting

1. If no display appears after tapping 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 for at least 30 minutes before repeating measurement.

3. If blood pressure is higher/lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
May not be in correct position while measuring.	Blood pressure naturally varies from time to time.
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.

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
Ĩ	Consult instructions for use	†	Type BF Equipment
	Manufacturer	Ĵ	Temperature limitation
SN	Serial number	X	Do not dispose of as household waste
IP22	Ingress protecting rating	CE ₀₁₂₃	CE mark
	Caution, consult accompanying documents	<u>(</u>	Humidity limitation
EC REP	Authorized representative in the European Community		

SPECIFICATIONS

System Performance Model No.: TD-3140 Size of Meter w/o Cuff: 145 (L) x 64.5 (W) x 29.6 (H) mm, 240 g Power Source: Four 1.5 V AAA alkaline batteries Power Saving: Automatic power off if system idle for 3 minutes Waterproof Grade: IP22 The Expected Service Life: 3 years 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

Blood Pressure Measurement Performance Systolic Measurement Range: 60 mmHg -255 mmHg Diastolic Measurement Range: 30 mmHg -195 mmHg Pulse Rate Measurement Range: 40 to 199 beats / minute Accuracy of Pressure: ±3 mmHg or ±2% of reading Accuracy of Pulse Rate: ±4% of reading Measurement Unit:

Fixed mmHg for meter, either mmHg or Kpa for App

This device has been tested to meet the electrical and safety requirements of: IEC/EN 60601-1, IEC/EN 60601-1-2, EN 301 489-17, EN 301 489-1, EN 300 328

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°.

NOTE

NOTE

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