tenovi

Cellular Blood Pressure Monitor

User Manual

Model #: TE-CBPL-B1

Made in China
Manufactured for Tenovi, Co.
1 Cate Street, STE 100,
Portsmouth, NH 03801
www.tenovi.com

Contact Information
Please contact your program's customer support. Tenovi will not be able to directly assist customers.

version: A/5

技术要求：
1、黏合不可露胶
2、保持印刷面板上的清洁
3、注意套印的准确性
4、表面处理不可爆开
5、须满足RoHS、Reach的环保要求
6、结构工艺以结构受控图为准
7、颜色参考：

2BF008189R□□P2/P23□

广东乐心医疗电子股份有限公司
2024-07-02
受 控 文 件

产品型号	BB2092-AA18-01-001		□□	105g□□□	零件名称	
产品名称	血压计		□□	210*145mm□□□105*145 mm□	2BF008509R-BB2092-AA18-01-001-GB-03-□□□-A1	
□□□□□□	-		□□	CMYK		
	比例	1:1	□□□□	-	零件图号	
	单位	mm	设计	李秋燕 2024-07-02	BB2092-AA18-01-001-GB-03	
Transtek 广东乐心医疗电子股份有限公司			审核	梁国威 2024-07-02	共 16 张	第 1 张
			批准	梁国威 2024-07-02	版 本	A/1

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INTRODUCTION

General Description

Thank you for choosing this Tenovi Cellular Blood Pressure Monitor.Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.
Please read this manual to know how to use your Blood Pressure Monitor safely and correctly. Keep the manual well for future reference.

Indications for Use

This Cellular Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm (6.3 to 14.1 inch), 22 to 42cm (8.6 to 16.5 inch), 22 to 45cm (8.6 to 17.7 inch) or 40 to 52cm (15.7 to 20.5 inch).
Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22-42cm (8.6 to 16.5 inch) and 40-52cm (15.7 to 20.5 inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.
It is intended indoor use only.

Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

INTRODUCTION

Safety Information

The symbols below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read. Note: The background color of the symbol is blue.		Type BF applied part
	Consult instructions for use or consult electronic instructions for use		Serial Number
	Direct Current		Polarity of d.c. power connector
	Class II Equipment		For indoor use only
	Batch code		Manufacturer
	Date of manufacture		Temperature limit
	Atmospheric pressure limitation		Humidity limitation
	General symbol for recovery/recyclable		
	MR Unsafe To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.		
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.		
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		

INTRODUCTION

Precaution

* Tenovi Cellular Blood Pressure Monitor is intended to be operated by adults, including medical staffs and lay persons. Adult patients could also be intended users or operators.
* This device is intended for indoor, home use and is not intended for self-use in public areas.
* This device is portable, but it is not intended for use during patient transport.
* This device is not suitable for continuous monitoring during medical emergencies or operations.
* This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
* This device is for patients who are at or over 3 years old. Do not use this device on neonates or infants.
* Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease, implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.
* If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
* This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
* Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
* The device may require up to 30 minutes to warm up / cool down from the minimum/ maximum storage temperature before it is ready for use.
* The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
* Do not wash the cuff in a washing machine or dishwasher !
* The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
* Please choose the appropriate cuff according to your arm circumference and physical health.

⚠ Caution

* Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
* It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact manufacturer or distributor for authorized service personnel.
* Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
* Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
* Dispose of accessories, detachable parts, and the device according to the local guidelines.

INTRODUCTION

Warning

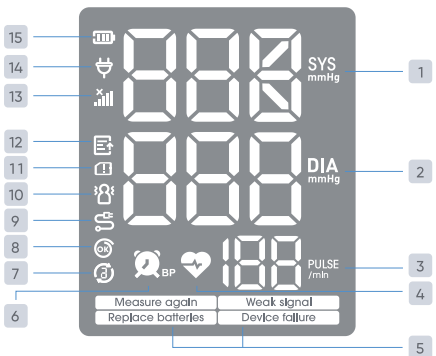
* DO NOT self-diagnose the measurement results and start treatment by yourself. The measurement results given by this device is not a diagnosis. ALWAYS consult your doctor for evaluation of the results and treatment.
* DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
* DO NOT apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
* DO NOT kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.
* Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
* DO NOT apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
* DO NOT place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
* DO NOT place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). it is recommended to take measurements on the unaffected side.
* DO NOT wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
* Warning: Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
* Warning: On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
* DO NOT use this device with high-frequency (HF) surgical equipment at the same time.
* This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.
* Excessive cuff tube lengths could cause strangulation if you don't manage them properly.
* DO NOT touch output of the batteries/adapter and the user simultaneously.
* The power cord is considered the disconnect device for isolating this equipment from supply mains. DO NOT position the equipment so that it is difficult to reach or disconnect.
* DO NOT use this device if you are allergic to polyester, nylon, or plastic.
* Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
* DO NOT use the device while under maintenance, or being serviced.
* Sensor degradation or looseness may reduce performance of device or cause other problems.
* The air tube poses a risk of strangulation. Furthermore, the small parts of product and batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.

Notice

* You can use this device to take your own measurement, no third-party operator is required.
* Adapter is specified as a part of ME EQUIPMENT.
* At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
* The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
* Please report to the manufacturer and the competent authority of the Member State / the FDA in which you are established about any serious incident that has occurred in relation to this device.

INTRODUCTION

Display and Symbols



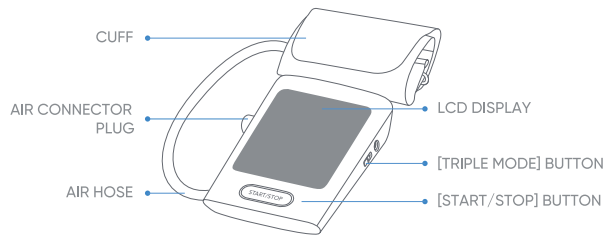
SYMBOL	EXPLANATION
1	Systolic blood pressure reading
2	Diastolic blood pressure reading
3	Pulse display
4	Irregular pulse rate symbol Appears when detected during a measurement. Refer to page 20 for more information.
5	Warning messages, refer to page 22 for more information.
6	Measurement reminder icon When it is activated, appear on the display and remind the user to measure at the certain time.

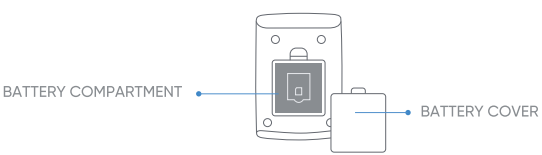
INTRODUCTION

SYMBOL		EXPLANATION
7		Triple Measurement icon Indicates the current measurement mode is [Triple Mode], and which measurement progress it is.
8		Cuff wearing detection icon will appear if the cuff is not wrapped or wrapped too loose or a leak of the cuff is detected when measuring.
9		Cuff abnormal icon Appears when the air connector plug is not properly plugged in .
10		Excessive body motion detector icon Appears when talking, moving, or shaking of the arm with the cuff on is detected during a measurement. NOTE: The measured blood pressure reading may not be accurate when this symbol is displayed with the reading.
11		SIM card error icon Appears when the SIM card is abnormal or the SIM is not properly plugged in.
12		Data pending to transmit icon Appears when the data transmission failed. Up to 500 measurements can be temporarily saved on the device and send to your account when the Cellular internet is available.
13		Signal indication icon Indicates no cellular coverage or cellular connection error.
14		Adapter Insert Indicator Appears when the power is supplied from the adapter.
15		Battery Indicator Indicate the current battery.
		Low battery symbol Indicate the battery is too low when appears with Replace batteries

INTRODUCTION

Name of Each Part





Contents/Product Includes

1 Tenovi Cellular Blood Pressure Monitor (TE-CBPL-B1)
1 Cuff (Type BF applied part)
- 16-36 cm (6.3-14.1 inch) upper arm cuff (Optional!)
- 22-42cm (8.6-16.5 inch) upper arm cuff (Optional!)
- 22-45 cm (8.6-17.7 inch) upper arm cuff
- 40-52cm (15.7-20.5 inch) upper arm cuff (Optional!)

1 User manual
4 "AA" size batteries (Installed in the device)

BEFORE YOU START

For your safety and optimal operation of the Tenovi Cellular Blood Pressure Monitor, do not connect any external power adapters. Using non-recommended power sources poses potential safety risks and may damage the device due to incorrect voltage and current specifications. As a power adapter is not provided, power the monitor exclusively with the specified batteries.

CAUTION

In order to get the best effect and protect your monitor, please use the right batteries and special power adapter which complies with local safety standard.

Installing and Replacing the Batteries

Please pull the plastic insulating strip before first use. The batteries were installed.

Replace the batteries whenever the below happens.

- Replace batteries appear on the LCD display.
- The display dims.
- The display does not light up.

Steps of replacing the batteries:

- Slide off the battery cover.
- Replace 4 AA size batteries according to the polarity indications inside the battery compartment.
- Place back the battery cover.

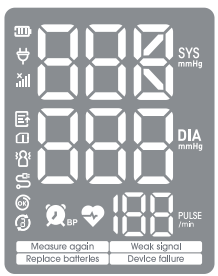
CAUTION

- New and used batteries, or different types of batteries shall not be used together.
- Remove batteries if the device is not likely to be used for some time.
- Do not heat or deform the batteries, or dispose of them in fire.
- Batteries should not be disposed of with household waste.
- Please check with your local authority for battery recycling advice.

BEFORE YOU START

Note A:
When you pull the plastic insulating strip or replace new batteries into the device, the LCD displays as below first, and then it will turn off after about 5 seconds.

LCD display



The device will then search and pair with the mobile network automatically after it is turned off. If unsuccessful, the monitor will stop searching and enter the standby mode.

Note B:
This device is equipped with function of Measurement Reminder. Contact Customer Support to enable or disable it, maximum 5 group of measurement Reminder (by default, the monitor will stop searching and enter the standby mode.

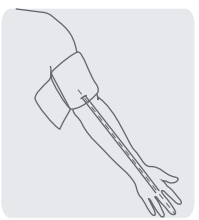
Once enabled, every day when the appointment time is reached, the blue LED of the device button will light up in the form of breathing light to remind the user to measure, and the breathing light will be cancelled after the startup or 30 minutes without operation. (If the user does not measure the blood pressure according to the reminder, the reminder icon of measurement will not be displayed when the user starts the measurement next time)

MEASUREMENT

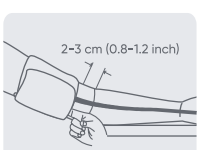
Applying the cuff

Only use a cuff that has been approved by the manufacturer for this device model. Before use, please confirm if it fits your arm circumference.

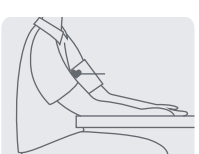
Choosing for cuff:
Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22-42cm (8.6 to 16.5 inch) and 40-52cm (15.7 to 20.5 inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.



1. Remove all jewelry, such as watches and bracelets from your left arm.
   Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.
2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
3. Hold your arm with palm facing up and tie the cuff on your upper arm, then align the air tube toward the center of your arm.
4. Make sure the bottom edge of the arm cuff 2-3 cm (0.8-1.2 inch) above the inside elbow. Then wrap the cuff securely.
   Note: The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



5. Sit upright in a comfortable chair with your back against the backrest of the chair. Keep your feet flat and your legs uncrossed.
   Place your arm resting comfortably on a flat table. The cuff worn on your arm should be placed at the same level as your right atrium of the heart.



6. Take 5-6 deep breaths and let's start measuring!

Helpful tips to help ensure an accurate reading

- Take the measurement in a silent room.
- Rest for 5 minutes before a measurement.
- Be relaxed, remain still and DO NOT talk while taking a measurement.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

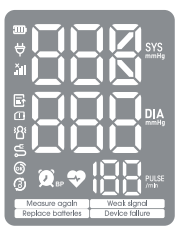
MEASUREMENT

A: Using Single Measurement Mode

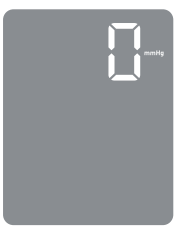
Start a measurement

When the "TRIPLE MODE" button is located on "1", the monitor is under the Single Measurement mode.
When the monitor is OFF, press the "START/STOP" button to turn on, and then it will complete the whole measurement automatically.

LCD display

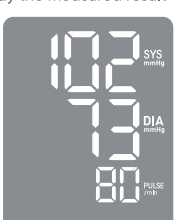


Adjust the zero point



Inflating and measuring

Display the measured result



MEASUREMENT

After the measurement, the data transmission starts. The symbol will appear on the LCD.

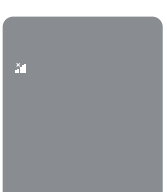
If successful, the symbol will disappear and the LCD will display OK.

Press "START/STOP" button to turn off the device, otherwise it will power off automatically within several seconds.

During the data transmission, if the data transmission error or server connection error occurs, the symbol will appear on the LCD. Up to 500 measurements can be temporarily saved on the device and send to your account when the Cellular internet is available. Refer to page 22 for more information.

This device is designed for a single user, which recorded BP data will be only assigned to this one user (account). The account of device corresponds to the IMEI number of the device, which is unique for traceability.

During the data transmission, if no cellular coverage or cellular connection error occurs, the symbol will appear on the LCD. Refer to page 22 for more information.



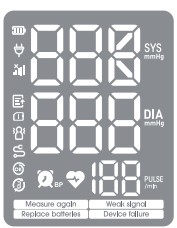
MEASUREMENT

B: Using Triple Measurement Mode

When the "TRIPLE MODE" buton is located on "3", the monitor is under the Triple mode.

1. When the monitor is off, press the "START/STOP" button to turn on, and then it will complete the whole measurement automatically.

LCD display



Display the zero point

Inflating and measuring

MEASUREMENT

2. When the first measurement is done, it won't show the readings. It will start the second measurement after 60 seconds.

3. Then it will repeat the steps to finish the third measurement. When three measurements are done, the LCD will display the average of 3 readings.

Tip:
If the measurement fails in the process of the Triple Measurement Mode, it will report an error and repeat the current measurement. If the error occurs for 3 times in a row, the Triple Measurement will automatically quit.

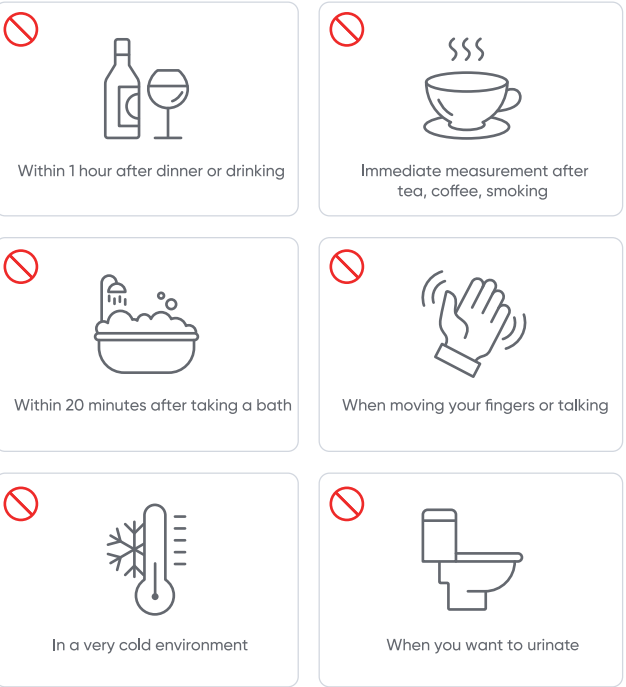
4. After the measurement, it will repeat the data transmission steps as described on pape 14.

Tip:
You can press the "START/STOP" button to stop the measurement any time.

INFORMATION FOR USER

Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



INFORMATION FOR USER

Maintenance

In order to get the best performance, please follow the instructions below.

1. Cleaning Process:
Step 1: Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.
Step 2: Clean the cuff with a soft cloth dampened with the soapy water. Until no visible contaminants remain.
Step 3: Rinse the cuff and wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
Step 4: Wipe off with a dry cloth to remove residual moisture.
Step 5: Air dry the cuff thoroughly after cleaning.

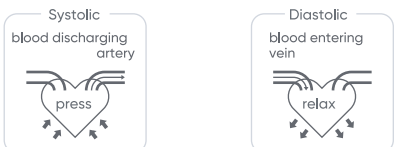
2. Disinfection Process (Clean the monitor before disinfection):
Step 1: Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.
Step 2: Disinfect the cuff with a soft cloth dampened with the 70% isopropanol during 3 minutes.
Step 3: Rinse the cuff and wipe off the disinfection solution with a fresh cloth or towel, dampened with tap water after disinfecting until no visible disinfection agent remains.
Step 4: Wipe off with a dry cloth to remove residual moisture.
Step 5: Air dry the cuff thoroughly after disinfecting.

- Suggestion:
Frequency of Cleaning and Disinfection:
For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.

ABOUT BLOOD PRESSURE

What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



What is the standard blood pressure classification?

The following chart is the standard blood pressure classification published by American Heart Association (AHA).

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Elevated	120–129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130–139	or	80–89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120

ABOUT BLOOD PRESSURE

CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Irregular Pulse Rate Detector

An irregular pulse rate will be detected if there is an irregular pulse rhythm while measuring systolic and diastolic blood pressure. When measurements were performed, the monitor will record all pulse intervals and calculate the average. If two or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±25% of the average; or if four or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±15% of the average value, the irregular pulse symbol will be displayed along with measurement results.

CAUTION

The appearance of the IPR icon indicates that a pulse irregularity consistent with an irregular pulse rate was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the irregular pulse rate detector results cannot be used directly for clinical judgement. Please seek medical advice from professionals before making any medical decisions.

ABOUT BLOOD PRESSURE

Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.

Why do I get different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:
If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.
Taking 2-3 deep breaths before beginning will be better for measuring.
Advice: Relax yourself for 4-5 minutes until you calm down.

Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people.
We suggest you measure the same arm every time.

TROUBLE SHOOTING

If any abnormality arises during use, please check the following points:

PROBLEM	DISPLAY	CHECK THIS	REMEDY
No power	Display can not light up.	Batteries are exhausted.	Replace with new batteries.
		Batteries are installed incorrectly or adapter is not plugged in properly.	Install the batteries or plug in the adapter properly.
DC Power Error	Err dc	The DC supply voltage is too high or too low.	Replace with the authorized adapter.
Low Battery	Replace batteries	The battery is too low.	Replace with new batteries.
Error message		The cuff is not wrapped or wrapped too loose.	Wrap and fasten the cuff and measure again.
		The air connector plug is not properly plugged in or a leak is detected.	Insert the air connector plug correctly, then measure again. If the issue persists, check the cuff leakage.
	Measure again	Excessive body motion (such as shaking of the arm with the cuff on) is detected.	Relax and then measure again. When the issue persists twice, E0 1will display on the LCD, please contact customer support.
	Measure again	Pulse is not detected during measuring.	Relax and then measure again. When the issue persists twice, E0 1will display on the LCD, please contact customer support or contact your physician.
	Measure again	Out of measurement range	
		Data transmission error or Server connection error	Move to another area, preferably closer to a window, try again. Use the device at a location where you get strong cellular signal with your mobile phone. If the issue persists, contact customer support.
	Weak signal	No cellular coverage or Cellular connection error	
		SIM card is not detected or SIM card is abnormal.	Check and re-install the SIM card. If the issue persists, contact customer support.
	Device failure	Hardware error	Retake measurement. If the issue persists, contact customer support.

NOTE: If the product still does not work, contact the Customer Service. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

SPECIFICATIONS

Product Name	Cellular Blood Pressure Monitor
External dimensions	Approx. 148.3 mm × 100.5 mm × 52 mm
Display mode	Digital LCD V.A. 79 mm × 93 mm
Weight	Approx. 325 g (Excluding the batteries and cuff)
Measurement mode	Oscillographic testing mode
Mode of operation	Continuous operation
Measurement range	Rated cuff pressure: 0 mmHg ~ 299 mmHg Measurement pressure: SYS: 60 mmHg ~ 230 mmHg DIA: 40 mmHg ~ 130 mmHg Pulse value: (40-199) beat/minute
Accuracy	Static Pressure: 5 ℃-40 ℃ within ±3mmHg Pulse value: ±5% Clinical validation: Mean difference within ±5mmHg; Standard deviation ≤8mmHg
Normal working condition	Temperature: +41°F to +104°F Relative humidity: 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa Atmospheric pressure: 700 hPa to 1060 hPa
Storage condition & transportation condition	Temperature: -4°F to +140°F Relative humidity: ≤93%, non-condensing, at a water vapour pressure up to 50 hPa Atmospheric pressure: 500 hPa to 1060 hPa
Measurement perimeter of the upper arm	About 16 to 36 cm (6.3 to 14.1 inch), 22 to 42cm (8.6 to 16.5 inch), 22 to 45cm (8.6 to 17.7 inch) or 40 to 52cm (15.7 to 20.5 inch).
Degree of protection	Type BF applied part
Device Classification	Battery Powered Mode: Internally Powered ME Equipment
Protection against ingress of water	IP21, It means the device could be protected against solid foreign objects of 12.5 mm Φ and greater, and against vertically falling water drops.
Expected Lifetime	Device: 5 years or 10000 measurements (may vary based on usage conditions) Cuff: 10000 times Alkaline battery: About 200-300 times
Software Version	A01
Types of use/reuse	Single patient multiple use

WARNING: No modification of this equipment is allowed.

AUTHORIZED COMPONENT

For your safety and optimal operation of the Tenovi Cellular Blood Pressure Monitor, do not connect any external power adapters. Using non-recommended power sources poses potential safety risks and may damage the device due to incorrect voltage and current specifications. As a power adapter is not provided, power the monitor exclusively with the specified batteries.

EMC GUIDANCE

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

Essential performance:
Accuracy of measuring blood pressure and pulse rate

Measurement Range	Systolic pressure: 60-230 mmHg Diastolic pressure: 40-130 mmHg Pulse: 40-199 beats/minute
Accuracy	Pressure: ±3mmHg Pulse value: ±5%

The Basis Safety of the Blood Pressure Monitor (TE-CBPH-B1) is as following:
Deviation from normal operation that poses an unacceptable risk to the patient or operator.

Warning: Don't be near the active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

EMC GUIDANCE

Technical description:
1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected lifetime.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test level	Compliance level
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines NA 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV, differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT ; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT ; 1 cycle and 70% UT ; 25/30 cycles; Single phase: at 0°. 0% UT ; 250 / 300 cycle	0% UT ; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT ; 1 cycle and 70% UT ; 25/30 cycles; Single phase: at 0°. 0% UT ; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430–470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

Specifications for 2G/4G

Specifications for 2G/4G			
		2G	4G
E-MTC/GSM	Supporting band :	GPRS/EGPRS: 850/1900	Cat-M1: B2/4/12/13/25
	Transmitted frequency range	824—849MHz, 1850—1910MHz	1850—1910MHz, 1710—1755MHz, 699—716MHz, 777—787MHz, 1850—1915MHz
	Transmitted power	850: 33±2dBm, 1900: 30±2dBm	20±2dBm
	Throughput	EGPRS:236.8-296Kbps GPRS: 85.6-107Kbps	375~1119 kbps
	Latency	＜500ms	≤ 21ms
	Jitter	＜500ms	≤ 21ms
	PER	＜10%	＜10%
	Data Integrity	Data shall be transmitted correctly and completely	
	Accessibility	Accessibility is high since 2G/4G is broadband	
	Signal Priority	Routine priority using 4G access standard	

Remark:

1.The Quality of Service (QoS) is considered as KPIs here.
2. For the Cellular Blood Pressure Monitor, the E-MTC is used to transmit the control data between the EUT and the controller, the manufacture considered 375~1119 kbps is a suitable throughput for the usage
3.The PER of the wireless system is normally less than 1%, for Semi-anechoic chamber, we considered the PER cannot be greater than 10%.
4. Use the wireless module which the EUT used as the test model,instead the EUT.

Warning

Failure to comply with the following warnings may cause cybersecurity issues.
DO NOT casually use the blood pressure monitor for others, as it may lead to leakage of personal measurement data.
DO NOT connect the blood pressure at places with poor network or wireless connectivity. as it may interrupt data upload and lead to deficient data.

FCC Statement

FCC ID: OU9TMB2092-G

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.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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.

FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Responsible Party
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Telephone: 301-910-0529
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