Teladoc HEALTH

HT2000 Connected Blood Pressure Monitor User Manual



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General Description

Thank you for choosing this Teladoc Health HT2000 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 Member Support.

Please read this manual to know how to use your blood pressure monitor safely and correctly. Keep the manual for future reference.

Manufacturing Information

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No. 105, Dongli Road,
Torch Development District, 528437
Zhongshan, Guangdong, China

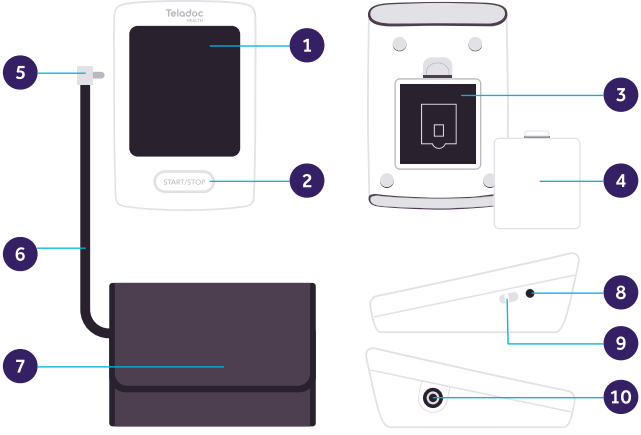
Manufactured for Teladoc Health, Inc.
1945 Lakepointe Drive
Lewisville, TX 75057

Contact Information

Member Support
(800) 945-4355
membersupport@teladochealth.com

Components of the Device

1. LCD display
2. START/STOP button
3. Battery compartment
4. Battery cover
5. Air connector plug
6. Air hose
7. Cuff
8. AC adapter port
   See page 19 for more information
9. TRIPLE MODE switch
10. Air connector port



Getting the Most Accurate Readings

The Teladoc Health HT2000 blood pressure monitor has been cleared by the FDA and validated for clinical accuracy. For the most accurate blood pressure readings:



Avoid caffeine, exercise and smoking for at least 30 minutes



Hold off until more than 20 minutes after a bath



Empty your bladder



Stay still



Be calm and quiet before taking a reading



Keep the room temperature comfortable

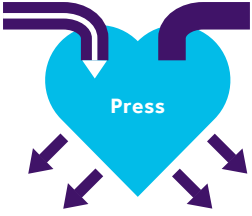


Wait until more than one hour after eating or drinking

Systolic and Diastolic Blood Pressure

When ventricles (the part of the heart that pumps blood) contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle. This is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle. This is called diastolic pressure.

Systolic



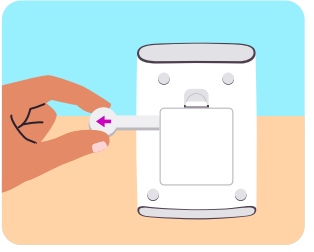
Blood is pumped out through arteries

Diastolic



Blood enters via veins

Prep for a Check



Remove plastic tab
Pull out the plastic strip before first use. Batteries are already installed.

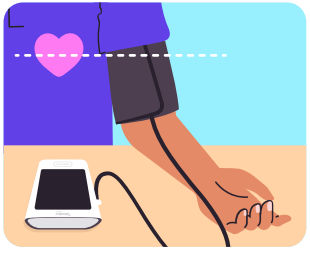


Plug in tube
Insert the air tube connector into the device.



Get ready for your reading
Rest for at least 5 minutes. Sit upright with both feet flat on the floor. Lay your arm on a flat, hard surface in front of you.

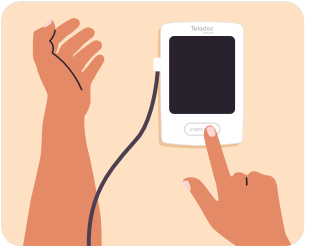
How to Check Your Blood Pressure



Put on the cuff
Wrap the cuff snugly around your bare upper arm at heart level. Make sure you can fit one finger in between the cuff and your arm.



Align the tube
Line the tube up with the inside of your arm.



Take your reading
Press the START/STOP button. Remain still and quiet while the cuff inflates and deflates completely. Your reading will then display.

Standard Blood Pressure Classification

The chart below is the standard blood pressure classification published by the American Heart Association (AHA). If you have been diagnosed with high blood pressure (hypertension), the AHA recommends keeping your blood pressure below 130/80 mmHg.

Blood Pressure Category	Systolic mmHg (upper number)		Diastolic mmHg (lower number)
Normal	Less than 120	and	Less than 80
Elevated	120-129	and	Less than 80
Stage 1 hypertension (high blood pressure)	130-139	or	80-89
Stage 2 hypertension (high blood pressure)	140 or higher	or	90 or higher
Severe hypertension (if you don't have symptoms*, call your health care professional.)	Higher than 180	and/or	Higher than 120
Hypertensive emergency (if you have any of these symptoms*, call 911.)	Higher than 180	and/or	Higher than 120

*Symptoms: chest pain, shortness of breath, back pain, numbness, weakness, change in vision or difficulty speaking

Indications for Use

This blood pressure monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 22 to 45 cm (8.6 to 17.7 inch) or 40 to 52 cm (15.7 to 20.5 inch).

Cuff model AC2245-021 has an arm circumference range of 22-45 cm (8.6 to 17.7 inches) and is intended for use in adults including those who are pregnant or have diabetes or pre-eclampsia.

Cuff model AC4052-04 has an arm circumference range of 40-52 cm (15.7 to 20.5 inches) and is intended for use in adults who are not pregnant or who do not have diabetes or pre-eclampsia,

It is intended for indoor use only.

Measurement Principle

This product uses the oscillometric measuring method to detect blood pressure.

Before every measurement, the unit establishes “zero pressure” equivalent to the atmospheric pressure. It then starts inflating the arm cuff. At the same time, the unit detects changes in pressure. This is used to determine the systolic and diastolic pressure and pulse rate.

Safety Information

Symbol	Description
	Refer to instruction manual/booklet. Note: The background color of the symbol is blue.
	Consult instructions for use or consult electronic instructions for use
	Direct current
	Class II equipment
	Batch code
	Date of manufacture

Symbol	Description
	Atmospheric pressure limitation
	Type BF applied part
	Serial number
	Polarity of D.C. power connector
	For indoor use only
	Manufacturer
	Temperature limit

Symbol	Description
	Humidity limitation
	General symbol for recovery/ recyclable
	MR unsafe: To identify an item that 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.

Symbol	Description
	Catalog number
	Keep away from sunlight
	Keep dry
	Fragile, handle with care
	This way up
	Stacking limit by number

Precautions

- This blood pressure monitor is intended to be operated by adults.
- This device is intended for indoor, home use and is not intended for 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 noninvasive 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 intended for adults. Do not use this device on neonates or infants. Do not use it on children or adolescents unless otherwise instructed by a medical professional.
- 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; or if you are undergoing intravascular therapy, have an arteriovenous shunt, or have had a mastectomy. Please note that any of these conditions may affect measurement readings, as can 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 specified 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 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, and 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 and cuff 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 local guidelines.

Warning

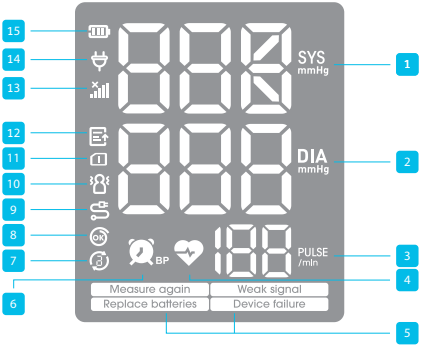
- DO NOT self-diagnose or start treatment by yourself. The measurement results given by this device are not a diagnosis. ALWAYS consult your doctor for evaluation of the results and treatment.
- DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed 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 in 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, e.g., 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 should not be used in conjunction with oxygen-rich environments, nor is it intended for use with flammable anesthetics or 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 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 START/STOP 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.
- 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 any serious incident that has occurred in relation to this device to the manufacturer and the FDA.

Display and Symbols

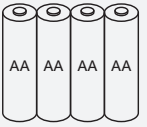


Symbol	Description
1	Systolic blood pressure reading
2	Diastolic blood pressure reading
3	Pulse display
4	Irregular pulse rate symbol Appears when detected during a measurement. Refer to page 28 for more information.
5	Warning messages, refer to page 31-32 for more information.
6	Measurement reminder icon When it is activated, it will appear on the display and remind the user to measure at the certain time.
7	Triple-measurement icon Appears during triple-measurement mode and indicates measurement progress ① ② ③.

Symbol		Description
8		Cuff 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.

Symbol		Description
12		Data pending to transmit icon Appears when the data transmission failed. Up to 500 measurements can be temporarily saved on the device and sent 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 See page 19 for more information.
15		Battery indicator Indicates the current battery level.
		Low battery symbol Indicates the battery is too low when appears with Replace batteries .

Power Supply



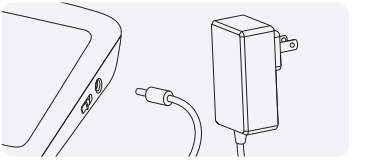
DC 6V, 4 AA size batteries

Always use four (4) AA size batteries to power the Teladoc Health HT2000 blood pressure monitor.

Any questions? Contact Teladoc Health Member Support at (800) 945-4355 or at **membersupport@teladochealth.com**.

Caution

DO NOT USE an AC adapter.



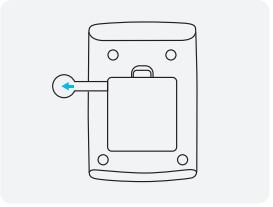
The AC adapter port on the Teladoc Health HT2000 blood pressure monitor is only intended for use by the manufacturer during the manufacturing process.

Type: BLJ06L060100P-U
Input: 100-240V, 50-60Hz, 0.2A max
Output: 6V ⎓ 1000 mA

Display	Description
	Adapter insert indicator Appears when the power is supplied from the adapter.
Err dc	**DC power error** The DC supply voltage is too high or too low.

Replacing the Batteries

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

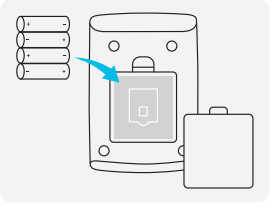


Replace the batteries whenever the below happens.

- Replace batteries appears 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.
- Replace the battery cover.



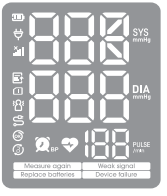
Caution

- New and used batteries, or different types of batteries should 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.

Note A:

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

The device will then search for 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 a measurement reminder function. Contact Member Support to enable or disable it.

Once enabled, a blue LED will light up to remind the user to measure each day at the set time. The light will go away after startup or 30 minutes without use. If the user does not measure blood pressure at the time of the reminder, the icon will not be displayed the next time the user begins measurement.

Applying the Cuff

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

Cuff selection depends on health conditions: Cuff model AC2245-021 (22-45 cm) is intended for adults, including those with diabetes, pregnancy, or pre-eclampsia. Cuff model AC4052-04 (40-52 cm) are for adults without these conditions. If you have any of these conditions or are not sure which cuff size is right for you, talk to a healthcare provider.

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 your 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 is 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 level of the right atrium of your heart.
6. Take 5-6 deep breaths and let's start measuring!

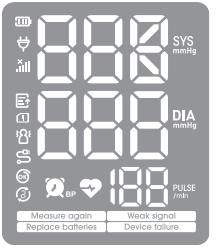
Helpful tips to help ensure an accurate reading

- 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.

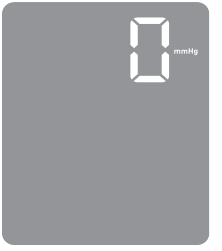
Using Single-Measurement Mode

Start a measurement

When the TRIPLE MODE switch is set to 1, the monitor is in 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.



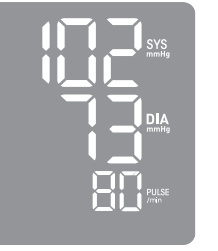
LCD display



Adjust the zero point



Inflating and measuring



Display the measured result

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 a 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 sent to your account when cellular internet is available. Refer to page 32 for more information. This device is designed for a single user and only assigns recorded BP data to one user account. The user account corresponds to the unique and traceable IMEI number of the device.



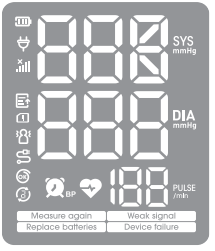
During data transmission, if there is no cellular coverage or cellular connection, the symbol will appear on the LCD. Refer to page 32 for more information.



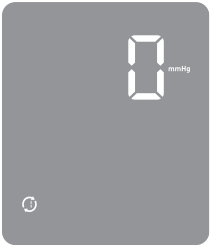
Using Triple-Measurement Mode

When the TRIPLE MODE switch is set to 3, the monitor is in triple-measurement mode.

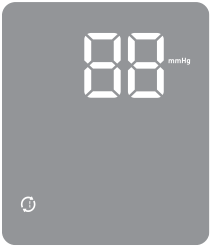
1. When the monitor is off, press the START/STOP button to turn on, and then it will complete the whole measurement automatically.



LCD display



Display the zero point



Inflating and measuring

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 the three readings.

Tip: If a measurement fails in triple-measurement mode, it will report an error and repeat the current measurement. If the error occurs 3 times in a row, triple-measurement will automatically quit.

4. After the measurement, it will repeat the data transmission steps as described on page 24.

Tip: You can press the START/STOP button to stop the measurement anytime.





Maintenance

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

Cleaning Process:

1. Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.
2. Clean the cuff with a soft cloth dampened with soapy water until no visible debris remains.
3. Rinse the cuff and wipe off cleaning solution with a clean, wet cloth. Wipe until no visible soap remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Air dry the cuff thoroughly after cleaning.

Disinfection Process (Clean the monitor before disinfection):

1. Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.
2. Disinfect the cuff with a soft cloth dampened with the 70% isopropanol for 10 minutes.
3. Rinse the cuff and wipe off the disinfection solution with a fresh cloth or towel dampened with tap water until no visible disinfection agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Air dry the cuff thoroughly after disinfecting.

Suggestion:

For single-patient use, clean the device surface once a month or whenever necessary.

Irregular Pulse Rate Detector

An irregular pulse rate is detected when a pulse rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculates the average:

- If there are two or more pulse intervals, and the difference between each interval and the average is more than the average value of ±25%; OR
- If there are four or more pulse intervals, and the difference between each interval and the average is more than the average value of ±15%;

In such cases, the irregular pulse rate symbol appears on the display when the measurement results appear.

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 device does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.

Frequently Asked Questions

Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies throughout the day. Blood pressure is also affected by how you secure your cuff and position your body during a reading. That's why it's important to use the same techniques each time you measure your blood pressure.
2. Blood pressure can also vary due to medication.
3. If you want to take another reading, wait 3 minutes and make sure you're using the the best techniques for blood pressure monitor accuracy.

Is the result the same if I use my other arm?

Some people will have different results depending on the arm they use.
We suggest you use the same arm each time.

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

Blood pressure can vary throughout the day. Many factors like the weather, emotions, activity level and more can impact your reading. Your blood pressure can be higher in clinical settings due to something called “white coat syndrome.”

When you measure your blood pressure at home, make sure:

- The cuff is applied correctly
- The cuff is not too tight or too loose
- The cuff is on your upper arm

Feeling anxious? Relax for 4-5 minutes and take 2-3 deep breaths before starting your reading.

Troubleshooting

Problem	Display	Check this	Remedy
No power	Display cannot light up.	Batteries are exhausted.	Replace with new batteries.
		Batteries are installed incorrectly.	Install the batteries properly.
Low battery	 Replace batteries	The battery is too low.	Replace with new batteries.
Error message		The cuff is not wrapped or is 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, will display on the LCD, please contact Member Support.
	 Measure again	Pulse is not detected during measuring.	Insert the air connector plug correctly, then measure again. If the issue persists, check the cuff leakage.

Problem	Display	Check this	Remedy
Error message		Out of measurement range.	Relax and then measure again. When the issue persists twice, E01 will display on the LCD; please contact Member Support.
		Data transmission error or server connection error.	Relax and then measure again. When the issue persists twice, E01 will display on the LCD; please contact Member Support or contact your physician.
		No cellular coverage or cellular connection error.	Move to another area, preferably closer to a window, and try again. Use the device at a location where you get a strong cellular signal with your mobile phone. If the issue persists, contact Member Support.
		SIM card is not detected or SIM card is abnormal.	Check and re-install the SIM card. If the issue persists, contact Member Support.
		Hardware error.	Retake measurement. If the issue persists, contact Member Support.

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

Technical Specifications

Product name	HT2000 Connected Blood Pressure Monitor
External dimensions	Approx. 148.3 mm x 100.5 mm x 52 mm
Display mode	Digital LCD V.A. 79 mm x 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 to 299 mmHg Measurement pressure: SYS: 60 mmHg to 230 mmHg DIA: 40 mmHg to 130 mmHg Pulse value: (40 to 199) beat/minute
Accuracy	Static pressure: 5°C to 40°C within ±3mmHg Pulse value: ±5% Clinical validation: Mean difference within ±5 mmHg; Standard deviation ≤8 mmHg
Normal working condition	Temperature: +41°F to +104°F Relative humidity: 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa Atmospheric pressure: 700 hPa to 1060 hPa

Storage condition and transportation condition	Temperature: -4°F to +140°F Relative humidity: ≤93%, non-condensing, at a water vapor pressure up to 50 hPa Atmospheric pressure: 500 hPa to 1060 hPa
Measurement perimeter of the upper arm	About 22 to 45cm (8.6 to 17.7 inch) or 40 to 52 cm (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, which 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 10,000 measurements (may vary based on usage conditions) Cuff: 10,000 times Alkaline battery: About 200 to 300 uses
Software version	A01
Types of use/reuse	Single-patient multiple use

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

The basis safety of the Blood Pressure Monitor (HT2000) is as following:
Deviation from normal operation that poses an unacceptable risk to the patient or operator.

Warning: Don't use near 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 12 inches (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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.

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

Warning:

Failure to comply with the following warnings may cause cybersecurity issues:

Please do not use this blood pressure monitor for multiple people. This could lead to leakage of personal data.

Please do not use the blood pressure monitor on a poor network or wireless connection. This could lead to interrupted and/or deficient data.

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 N/A 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% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
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 AC main's voltage prior to application of the test level.

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 18Hz	1.8	0.3	27	27
450	430-470	GMRS 460, FRS 460	FM ± 5kHz deviation 1kHz sine	2	0.3	28	28
710 745 780	704-787	LTE Band 13,17	Pulse modulation 217Hz	0.2	0.3	9	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4,25; UMTS	Pulse modulation 217Hz	2	0.3	28	28
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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9

California Proposition 65 Warning



WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

For more information visit: www.P65Warnings.ca.gov

The California Office of Environmental Health Hazard Assessment (OEHHA) has added vinyl acetate to the California list of chemicals known to cause cancer under California Proposition 65.

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 20 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Your Welcome Kit includes:

- 1 Blood Pressure Monitor (HT2000)
- 1 Cuff (Type BF applied part)
- 22-45 cm (8.6-17.7 inch) Upper Arm Cuff
- 40-52 cm (15.7-20.5 inch) Upper Arm Cuff (ships separately, if needed)
- 2 User Manuals (English and Spanish)
- 1 Travel Case
- 4 AA Batteries (installed in the device)

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