

iHealth® Track

Connected Arm Blood Pressure Monitor OWNER'S MANUAL



MEASURING BLOOD PRESSURE – A FEW BASICS

Blood Pressure Monitor that uses the oscillometric principle to measure your blood pressure and pulse rate. Blood pressure fluctuates continually day and night. Any physical activity or excitement will influence your blood pressure. Because of this, it is unusual to obtain identical multiple blood pressure readings. This is why it is recommended that you measure your blood pressure at approximately the same time every day.

PACKAGE CONTENTS

- 1 BP Track blood pressure monitor
- 1 Cuff
- 1 User Guide
- 4 AAA Batteries

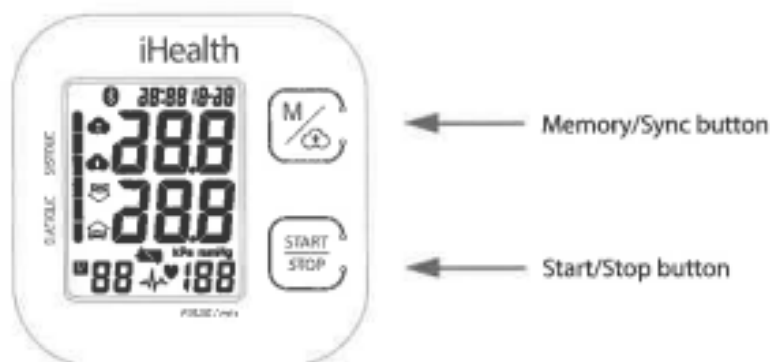
1. Relax for 5 minutes before taking your blood pressure.
2. Sit comfortably at a table when measuring your blood pressure.
3. The cuff should be placed at the same level as your heart.
4. Do not talk or move during a measurement.
5. Use the same arm every time.
6. Remove the batteries from the device if it is not used for a month or more to avoid battery leakage.
7. This blood pressure monitor is designed for adults and should not be used on children.
8. It is not recommended for people with serious arrhythmia to use this device.
9. Do not use any other cuff than the one supplied by iHealth.
10. Relax...

WHAT YOUR DEVICE SHOULD LOOK LIKE

The explanation of symbols on the display:

- Bluetooth Symbol
- Synchronization Symbol
- Release Air Symbol
- Memory Indicator

-  Low Battery Indicator
-  Irregular Heartbeat Symbol
-  Blood Pressure Level Classification Indicator



WHY YOU SHOULD CONNECT YOUR DEVICE

Taking a measurement is easy. It's what you do with the measurement that is important. You can use your device as a stand-alone device just to measure your blood pressure, but when you connect it to the free **iHealth MyVitals** App you will be able to track, store, manage and share your results with your family, doctor or care givers. Simply download iHealth MyVitals on the Apple App Store or Google Play Store and start managing your health.

Your iHealth account also gives you access to the free and secure iHealth cloud service so that you can manage your data, watch your trends and share your data. To do this, visit cloud.ihealthlabs.com and log in

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using the same account as you used with your App.


The iHealth Track Blood Pressure Monitor is designed to be used with *Bluetooth Smart* Apple devices and selected *Bluetooth Smart* Android smartphones. Please note that the compatible devices are subject to change. For the latest compatibility list visit www.ihealthlabs.com/support.

HOW TO USE YOUR BLOOD PRESSURE MONITOR

1. BATTERIES

- Open the battery cover on the back of the device.
- Insert 4 AAA batteries, paying attention to the direction.
- Close the battery cover.

 When the display shows the battery symbol (), replace all the batteries with new ones.

 Rechargeable batteries are not suitable for this monitor.

 The monitor, the batteries and the cuff must be disposed of according to local regulations at the end of their usage.

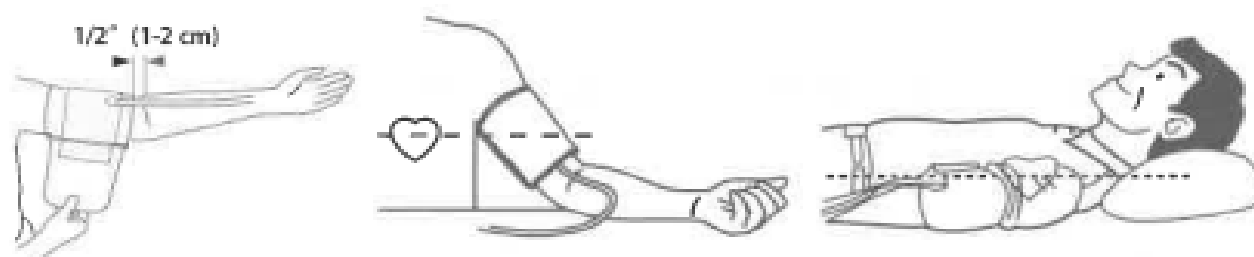
2. HOW TO PLACE THE CUFF ON YOUR ARM

The iHealth Track Blood Pressure Monitor comes in 2 cuff sizes. The standard cuff will fit arm circumferences between 8.6" to 16.5" (22cm to 42cm) and the XL cuff will fit arm circumferences from 16.5" to 18.9" (42cm to 48cm).

- Place the cuff tube downwards, around a bare arm about 1/2" (1 - 2cm) above the elbow joint.

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b. Sit with your feet flat on the floor without crossing your legs. While seated, place your palm side up in front of you on a flat surface such as a table. Lying Down During Measurement: (You can also lie on your back and place your left arm straight along your side with your hand palmside up.) Position the air tube in the middle of your arm in line with your middle finger.



c. Close the cuff with the Velcro fastener.

d. The cuff should fit comfortably around your arm.

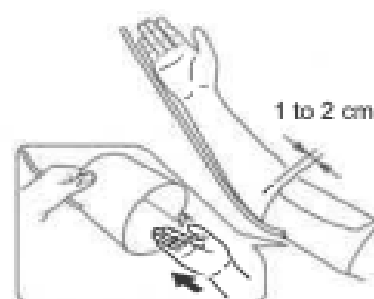
You should be able to insert one finger between your arm and the cuff.

Taking a Reading on the Right Arm

Apply the cuff so that the air tube is at the side of your elbow.

Notes:

- Be careful not to rest your arm on the air tube, or otherwise restrict the flow of air to the cuff.
- The cuff should be 1 to 2 cm above the elbow.



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Note: If the cuff becomes dirty, remove it from the monitor and wipe it with a lightly moistened soft cloth. Then air-dry the cuff. Do not machine wash. Cleaning the cuff after every 200 measurements is recommended.

3. CONNECTING THE CUFF TO THE DEVICE

Once you have determined the correct cuff size (Standard cuff: 8.6" to 16.5" (22cm to 42cm) or XL cuff:

16.5" to 18.9" (42cm to 48cm), simply insert the cuff connector into the air port on the side of the monitor.

Ensure that the connector is completely inserted to avoid air leakage.

Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

4. SETTING THE DATE AND TIME

Insert the batteries in the device and connect it with the iHealth MyVitals App on your smartphone. The time and date will automatically be updated. If you change the batteries, please re-adjust the time and date again.

5. TAKING A BLOOD PRESSURE MEASUREMENT

a. After placing the cuff on your arm and relaxing for a few minutes, press the "START/STOP" button. All display characters are shown for self-test, please contact the service center if segment is missing.

b. The monitor will inflate the cuff and then slowly release pressure from the cuff as the blood pressure is measured. When the measurement is finished the blood pressure and pulse rate will be displayed on the display. The blood pressure will be displayed in different colors (green for normal, yellow for slightly elevated, and red for high) according to the recommendations of the WHO (World Health Organization). The result will automatically be stored in the memory bank of the monitor.

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c. If an Irregular Heartbeat (IHB) is detected during a measurement, the IHB symbol will be displayed (blinking). If an IHB is detected, the results of the blood pressure measurement may be inaccurate. Please consult your physician for an accurate assessment.

d. At any time you can synchronize your device with the iHealth MyVitals App so that you can better manage your blood pressure.

e. The monitor will automatically switch off after one minute to save batteries. Alternatively, you can press the "START/STOP" button to turn off the monitor manually.

f. At any time during a measurement, you can interrupt a measurement by pressing the "START/STOP" button.

CLASSIFICATION OF BLOOD PRESSURE AND BACKLIGHT INDICATOR

| BLOOD PRESSURE CLASSIFICATION | Systolic mmHg | Diastolic mmHg | BACKLIGHT INDICATOR |
|-------------------------------|---------------|----------------|---------------------|
| Optimal | 91-119 | and 61 - 79 | Green |
| Normal | 120-129 | and 80 -84 | Green |
| High-normal | 130-139 | or 85 - 89 | Yellow |
| Grade 1 Hypertension | 140-159 | or 90 - 99 | Flashing Yellow |
| Grade 2 Hypertension | 160-179 | or 100-109 | Red |
| Grade 3 Hypertension | ≥180 | or ≥110 | Flashing red |

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6. MEMORY

You can review previous readings by pressing the "M" button twice. The first memory displayed will be the average of the last three measurements. When the average of the last three measurements is displayed, press the "M" button, the newest measurement will display. Press "M" button again to review the next measurement. During the display of saved measurements, hold the "M" button for three seconds to delete all measurements from memory.

If there are no saved measurements, the display will show zero.

The monitor will automatically switch off after one minute to save batteries. Alternatively, you can press the "START/STOP" button to turn off the monitor manually.


7. SYNCHRONIZING WITH THE IHEALTH MYVITALS APP

Before you can synchronize all your blood pressure readings, you need to download the iHealth MyVitals App on your smartphone from the Apple App Store or Google Play Store. You then need to create your own iHealth account in the App.

To synchronize:

1. Place your phone next to your blood pressure monitor.
2. Start the iHealth MyVitals App on your smartphone (ensure that your Bluetooth is activated in your settings).
3. Press the "M" (Memory) button on the monitor. The number of saved measurements will be displayed. After a few seconds, the monitor will automatically start to sync the measurements to the MyVitals App. While it is syncing, you will see the measurement numbers decrease on the display until it reaches zero.
4. If there are no saved measurements, the display will show zero.


8. TROUBLESHOOTING


| Problem | Explanation | Solution |
|--|--|--|
| LCD shows low battery symbol  | Low Battery | Change all the batteries |
| LCD shows "Er 0" | Pressure is unstable before measurement | Try again without moving |
| LCD shows "Er 1" | Failed to detect systolic pressure | |
| LCD shows "Er 2" | Failed to detect diastolic pressure | |
| LCD shows "Er 3" | Pneumatic system blocked or cuff is too tight during inflation | Apply the cuff correctly and try again |
| LCD shows "Er 4" | Pneumatic system leakage or cuff is too loose during inflation | |
| LCD shows "Er 5" | Cuff pressure above 300mmHg | Measure again after 5 minutes. If the error persists, please contact iHealth customer support. |
| LCD shows "Er 6" | More than 3 minutes with cuff pressure above 15 mmHg | |
| LCD shows "Er 7" | Memory accessing error | |
| LCD shows "Er 8" | Device parameter checking error | |
| LCD shows "Er A" | Pressure sensor error | |
| No response when pressing buttons or after installing batteries | Incorrect operation or strong electromagnetic interference. | Take out the batteries, wait five minutes and then reinstall batteries |

Please visit ihealthlabs.com/support for more information and frequently asked questions.

9. GENERAL SAFETY AND PRECAUTIONS

- Carefully read the user guide before operating the device.
- Consult your physician for any of the following situations:
 - The application of the cuff over a wound or inflamed area.
 - The application of the cuff on the arm on the side of a mastectomy.
 - Simultaneous use with other medical monitoring equipment on the same limb.
 - The application of the cuff on any limb with intravascular access or therapy, or an arteriovenous (A-V) shunt.
 - The blood circulation of the user needs to be checked.
- Do not use this product in a moving vehicle as this may result in inaccurate measurements.
- The IHB symbol will be displayed under 2 sets of circumstances:
 - The coefficient of variation (CV) of pulse period >25%.
 - The difference of adjacent pulse period is $\geq 0.14s$ and more than 53% of the total number of pulses readings falls within this definition.
- Please do not use any cuff other than that supplied by the manufacturer as this may result in inaccurate measurements.
- The monitor will show "Hi" or "Lo" as technical alarm on LCD with no delay if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS. In this case, you should consult a physician or check if your operation violated the instructions. The technical alarm condition (outside the rated range) is pre-set in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8. The technical alarm is non-latching and needs no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.

 This Monitor is designed for adults and should never be used on infants, young children or patients with preeclampsia.

 This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

- ⚠ Please do not share the cuff with any infectious person to avoid cross-infection.

The monitor, cable, battery and cuff must be disposed of according to local regulations at the end of their usage.

- ⚠ The patient is an intended operator.
- ⚠ Keep the device out of the reach of children/pets to avoid inhalation or swallowing of small parts.
- ⚠ If you are allergic to plastic/rubber, please don't use this device.

7. Prolonged over-inflation of the bladder may cause bruises of your arm.

10. CARE AND MAINTENANCE

1. Do not drop the monitor or subject it to strong impacts.
2. Avoid high temperature and direct exposure to the sun. Do not immerse the monitor in water.
3. If this monitor is stored near freezing temperatures, allow it to acclimate to room temperature before use.
4. Do not attempt to disassemble this monitor.
5. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended that the performance of this monitor be checked every 2 years.
7. Please clean monitor with a soft dry cloth. Do not use any abrasive or volatile cleaners.
8. The supplier will make available on request the circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.
9. It is recommended that if the cuff is used in a hospital or a clinic, it be disinfected twice a week. Wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then air dry the cuff.
10. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open -close cycles of the closure.

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11. Not servicing/maintenance while the monitor is in use.

11. WARRANTY INFORMATION

The iHealth Track Wireless Blood Pressure Monitor is warranted to be free from defects in materials and workmanship within one year from the date of purchase when used in accordance with the provided instructions. The warranty extends only to the end user. We will, at our option, repair or replace without charge the iHealth Track Wireless Blood Pressure Monitor covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

If you have any questions regarding the aftersales or usage of the product, please visit www.ihealthlabs.com and consult our Frequently Asked Questions on blood pressure (in our support section). If you do not find the answers you are looking for, please send us a query directly from the website. If you have any suggestions so that we can improve our products, please send us a mail at support@ihealthlabs.com.

12. EXPLANATION OF SYMBOLS ON PACKAGING



Symbol for "THE OPERATION GUIDE MUST BE READ"
(The sign background color: blue. The sign graphical symbol: white.)



Symbol for "Warning"



Symbol for "Manufacturer"

CE 0197

CE conformity mark



Symbol for "Type BF Applied Parts" (cuff only)



Symbol for "SERIAL NUMBER"



Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice".



Symbol for "Country of manufacture"
and "Date of manufacture"



Symbol for "EUROPEAN REPRESENTATIVE"

IP21 The first characteristic numeral symbol for "Degrees of protection against access to hazardous parts and against solid foreign objects ". The second characteristic numeral symbol for "Degrees of protection against ingress of water"

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13. SPECIFICATIONS

Product name: iHealth Track Blood Pressure Monitor

Model: KN-550BT

Classification: Internally powered, type BF applied part; IP21, No AP or APG; Continuous operation

Machine size: 38.6" x 38.6" x 18.1" (9.8 x 9.8 x 4.6 cm)

Cuff circumference: Standard cuff: 8.6" to 16.5" (22cm to 42cm)

XL cuff: 16.5" to 18.9" (42cm to 48cm).

Weight: 348g (batteries and cuff included)

Measuring method: oscillometric method, automatic inflation and measurement

Memory storage: 99 measurements

Power source: 4x1.5V SIZE AAA batteries

Measurement range:

Cuff pressure: 0 - 300mmHg

Systolic: 60 - 260mmHg

Diastolic: 40 - 199mmHg

Pulse rate: 40 - 180 beats/minute

Wireless communication: *Bluetooth* V4.1 BLE only mode

Frequency Band: 2.400-2.4835 GHz

Measuring accuracy: Pressure: ± 3 mmHg, Pulse rate: $\pm 5\%$

Environmental temperature for operation: 10 ~ 40°C

Environmental humidity for operation: $\leq 85\%$

Environmental temperature for storage: -20 ~ 50°C

Environmental humidity for storage: $\leq 85\%$

Environmental pressure: 80 ~ 105kPa

Battery life: Approximately 250 readings

This blood pressure measurement system includes accessories: pump, valve, cuff, and sensor.

Note: These specifications are subject to change without notice.

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This device bears the CE conformity mark. The quality of this wireless device has been verified and conforms to the provisions of the IEC 60601-1 Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 (Medical electrical equipment – Part 1: General requirements for safety); IEC 60601-1-2:2014/EN 60601-1-2:2015 (Medical electrical equipment – Part 1: General requirements for safety; Collateral Standard-Electromagnetic compatibility - Requirements and tests); EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements); EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems); IEC 60601-2-30:2018/EN IEC 60601-2-30:2019 (Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).

For information regarding potential electromagnetic or other interference between the iHeath Track Blood Pressure Monitor and other devices together with advice regarding avoidance of such interference, please visit www.ihealthlabs.eu/support/electromagnetic. It is suggested that the Wireless Blood Pressure Monitor should be operated at least 10 metres away from electric or wireless devices (e.g. routers, microwave oven, etc.).

IMPORTANT INFORMATION REQUIRED BY THE FCC

This device complies with Part 15 of the FCC Rules. Its 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.
- Changes or modifications not expressly approved by ANDON HEALTH CO., LTD. would void the user's authority to operate the product.

Note: This product 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 product 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 product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

This product complies with Industry Canada IC: RSS-210

IC NOTICE

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

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

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, Bluetooth modulation types:GFSK , effective radiated power: < 4 dBm

Table 1 - Emission

| Phenomenon | Compliance | Electromagnetic environment |
|----------------------------------|---------------------------|-----------------------------|
| RF emissions | CISPR 11 Group 1, Class B | Home healthcare environment |
| Harmonic distortion | IEC 61000-3-2 Class A | Home healthcare environment |
| Voltage fluctuations and flicker | IEC 61000-3-3 Compliance | Home healthcare environment |

Table 2 - Enclosure Port

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|--------------------|--|
| | | Home Healthcare Environment |
| Electrostatic Discharge | IEC 61000-4-2 | ±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 10V/m 80MHz-2.7GHz 80% AM at 1kHz |
| Proximity fields from RF wireless communications equipment" | IEC 61000-4-3 | Refer to table 3 |
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30A/m 50Hz or 60Hz |

Table 3 – Proximity fields from RF wireless communications equipment

| Test frequency (MHz) | Band (MHz) | Immunity test levels |
|----------------------|------------|--|
| | | Professional healthcare facility environment |
| 385 | 380-390 | Pulse modulation 18Hz, 27V/m |
| 450 | 430-470 | FM, ±5kHz deviation, 1kHz sine, 28V/m |
| 710 | 704-787 | Pulse modulation 217Hz, 9V/m |
| 745 | | |
| 780 | | |
| 810 | | |
| 870 | 800-960 | Pulse modulation 18Hz, 28V/m |
| 930 | | |
| 1720 | | |
| 1845 | | |
| 1970 | 1700-1990 | Pulse modulation 217Hz, 28V/m |
| 2450 | | |
| 5240 | 2400-2570 | Pulse modulation 217Hz, 28V/m |
| 5500 | | |
| 5785 | | |
| | 5100-5800 | Pulse modulation 217Hz, 9V/m |
| | | |

