iHealth® Track

Connected Blood Pressure Monitor
Instruction Manual

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INTRODUCTION

Thank you for selecting the iHealth Track Blood Pressure Monitor. The iHealth Track Blood Pressure Monitor is a fully automatic arm-cuff blood pressure monitor that uses the oscillometric principle to measure your blood pressure and pulse rate. The monitor works with your mobile devices to track and share vital blood pressure data.

BOX CONTENTS

- Track Blood Pressure Monitor
- Cuff
- Instruction Manual
- 4 AAA Batteries

INTENDED USE

iHealth Track Blood Pressure Monitor is for medical professionals or individuals (patients) at home. It is a non-invasive blood pressure measurement system intended to measure the diastolic blood pressure, systolic blood pressure, and pulse rate of an adult individual using a non-invasive technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 8.6"-18.9" (22-48cm).

CONTRAINDICATION

⚠ This Blood pressure monitor (Electronic Sphygmomanometer) is unsuitable for people with severe arrhythmia.

CONTENTS AND DISPLAY INDICATORS

Memory/Sync button

Start/Stop button

The explanation of symbols on display:

- Bluetooth Symbol
- Memory Indicator
- Irregular Heartbeat Symbol
- Release Air Symbol
- Low Battery Indicator
- Blood Pressure Level Classification Indicator

IMPORTANT INFORMATION ABOUT BLOOD PRESSURE MEASUREMENT

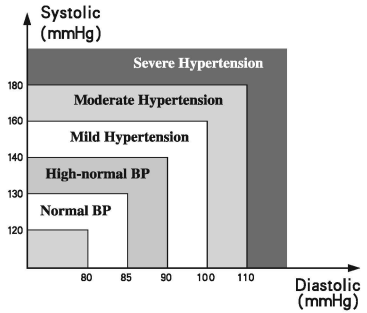
1. NORMAL BLOOD PRESSURE FLUCTUATION

Blood pressure is affected by various factors, including excitement, stress, body position, and physical activities such as eating, drinking, and smoking. As a result, it is unusual to obtain identical blood pressure readings multiple times.

Blood pressure constantly fluctuates throughout the day and night. Typically, blood pressure rises during the day and peaks while most people are awake and active. It then drops in the evening, reaching its lowest while most people sleep.

Considering the above information, measuring your blood pressure at approximately the same time every day is recommended.

2. BLOOD PRESSURE CLASSIFICATION FOR ADULTS



BLOOD PRESSURE CLASSIFICATION	Systolic mmHg	Diastolic mmHg	BACKLIGHT INDICATOR
Optimal	<120	<80	Green
Normal	120–129	or 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

WHO Definitions and Classification of Blood Pressure Levels.

GENERAL SAFETY AND PRECAUTIONS

The blood pressure monitor is not intended to exposed to the Electromagnetic Interference (EMI) environment, ⓂⓇ please do not use the blood pressure monitor within the environment of the following device: Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), and electromagnetic security systems such as metal detectors.

1. Read all the information in the Instruction Manual before operating the unit.
2. Consult your physician for any of the following situations:

a) Applying the cuff over a wound or inflamed area.
b) Applying the cuff on any limb with intravascular access or therapy or an arteriovenous(A-V) shunt.
c) Applying the cuff on the arm on the side of a mastectomy or lymph node clearance.
d) Simultaneous use of other medical monitoring equipment on the same limb.
e) The blood circulation of the user needs to be checked.

3. Do not use this product in a moving vehicle to ensure measurement accuracy.
4. Blood pressure measurements determined by this product are equivalent to those obtained by professional healthcare practitioners using the cuff/stethoscope auscultation method within limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers.
5. If an Irregular Heartbeat (IHB) is detected during the measurement procedure, the IHB symbol will be displayed in the measurement result; but the blood pressure measurement results may be inaccurate. Please consult your physician for an accurate assessment.

The IHB symbol will be displayed under 2 conditions:

1) The pulse period's coefficient of variation (CV) is>25%.
2) The difference of adjacent pulse period is ≥0.14s, and more than 53 percent of the total number of pulse readings falls within this definition.

6. Please do not use any cuff other than that supplied by the manufacturer, as this may result in inaccurate measurements.
7. For information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices and advice regarding avoiding such interference, please see ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the blood pressure monitor be kept 30 cm away from other wireless devices, such as WLAN units, cell phones, microwave ovens, etc.
8. If the blood pressure measurement (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS, the monitor will immediately display a technical alarm on the LCD screen. In this case, repeat the measurement, ensure that proper measurement procedures are followed, or consult your medical professional. The technical alarm is preset in the factory and cannot be adjusted or inactivated. This technical alarm is assigned as a low priority according to IEC 60601-1-8. The technical alarm does not need to be reset. It can't be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magneticresonance imaging, where the intensity of EM DISTURBANCES is high.
9. Measurements are not possible in patients with a high frequency of arrhythmias.
10. The device is not intended for infants, children, or pregnant women. (Clinical testing has not been conducted on infants, children, or pregnant women.)
11. Motion, trembling, and shivering may affect the measurement reading.
12. The device is not advisable for patients with poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position).
13. The device would not apply to patients who use an artificial heart and lung (there will be no pulse).
14. Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pre-eclampsia, and renal diseases.

15. The patient is an intended operator.
16. Swallowing batteries or battery fluid is extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.
17. Too frequent measurements may cause injury due to blood flow interference.
18. If you are allergic to plastic/rubber, please don't use this device.
⚠ This blood pressure monitor is designed for adults and should never be used on infants or young children below 12. Consult with your physician or other health care professionals before use on older children.
⚠ 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.

SETUP AND OPERATING PROCEDURES

1. DOWNLOAD THE APP (Recommended)

Before first use, download and install the iHealth Myvitals app from the App Store (iOS device) or Google Play (Android device). Use the search term "Myvitals."

2. INSTALL BATTERIES

a. Open the battery cover on the back of the blood pressure monitor.
b. Insert four "AAA" batteries as indicated in the battery compartment.
c. Close the battery cover.

Note:

- When the battery symbol  shows on display, replace batteries with new ones.
- Rechargeable batteries are not suitable for this blood pressure monitor.
- Remove the batteries if the blood pressure monitor will not be used for at least a month to avoid potential damage from battery leakage.

⚠ Avoid getting the battery fluid in your eyes. If battery fluid gets in your eyes, immediately rinse with clean water and consult with your physician.

⚠ The negative(-) side of the battery should be touching the spring.

⚠ Ensure the battery cover is intact and not damaged before installing the battery.

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

3. CONNECT THE CUFF TO THE MONITOR

The iHealth Track Blood Pressure Monitor is available 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).

To connect the cuff to the monitor, simply insert the cuff connector into the air hole on the monitor's side.

Note:

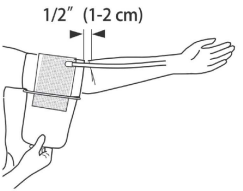
- Make sure that the connector is completely inserted to avoid air leakage.
- Avoid compression or restriction of the connection tube during measurement, which may cause inflation error or injury due to continuous cuff pressure.

4. APPLY THE CUFF

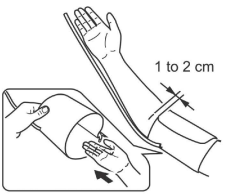
a. Place a bare arm through the cuff and position the cuff ½"(1-2cm) above the elbow joint with the cuff tube pointing downward.

If applied on the left arm: Position the cuff so that the cuff tube is in the middle of your arm and in line with your middle finger.

If applied on the right arm: Position the cuff so that the cuff tube is at the side of your elbow and in line with your little finger.



Left arm measurement



Right arm measurement

b. Sit with your feet flat on the floor without crossing your legs. While seated, place your palm on a flat surface, such as a table, in front of you.

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.

Note:

- Be careful not to rest your arm on the air tube or otherwise restrict air flow to the cuff.

5. BODY POSTURE DURING MEASUREMENT

• Sitting during measurement

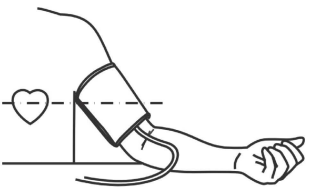
a. Sit with your feet flat on the floor. Do not cross your legs.

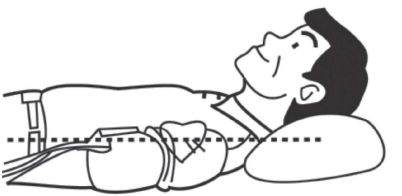
b. Place your elbow on a table, with your palm facing upward in front of you.

c. Your cuff should be approximately the same level as your heart. If the monitor is too high or too low below your heart, your blood pressure will be artificially low or high.

• Lying down during measurement

You can also lie on your back and place your left arm straight along your side with your hand palm up. Position the air tube in the middle of your arm in line with your middle finger.





6. TAKE A BLOOD PRESSURE MEASUREMENT

a. After applying the cuff and making sure your body is in a proper position, press the "START/STOP" button, and all symbols will show on display. Please contact customer service if some symbols are missing.

b. The monitor will inflate the cuff and 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 shown on the display. The blood pressure will be displayed in different colors (green indicates Optimal or Normal, orange indicates Normal-High or Hypertension type 1, and red indicates Hypertension type 2 or 3) according to the recommendations of the WHO (World Health Organization). The result will automatically be stored in the memory bank of the monitor.
c. If an Irregular Heartbeat (IHB) is detected during a measurement, the IHB symbol will be displayed. If an IHB is detected, the blood pressure measurement results may be inaccurate. Please consult your physician for an accurate assessment.
d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the "START/STOP" button to turn off the monitor manually.
e. At any time during a measurement, you can interrupt a measurement by pressing the "START/STOP" button.
Note:
• Please refer to the measurable arm circumference in "SPECIFICATIONS" to ensure the cuff is suitable for use.
• Measure on the same arm each time.
• During measurement, do not talk or move your arm, body, or monitor.
• Stay still, and rest for 5 minutes before taking the measurement.
• Remove the cuff from the monitor and wipe it with a lightly moistened soft cloth if the cuff becomes dirty. Then air-dry the cuff. Do not machine wash. Cleaning the cuff after every 200 measurements is recommended.

• Do not place the cuff around your arm if your arm has any inflammation, acute diseases, infection, or skin wounds.
• Please consult with a healthcare professional for the interpretation of measurements.

7. VIEW AND DELETE STORED READINGS

a. Review previous readings by pressing the "M" button twice. The first memory displayed will be the average of the last three measurements. If no readings are stored, the display will show zero.
b. When the average reading of the last three measurements is displayed, press the "M" button to display the most recent readings. Continue pressing the "M" button to view the next reading.
c. When a reading is displayed, holding the "M" button for seven seconds will remove all the readings stored on the device.

8. SYNCHRONIZE STORED RESULTS WITH THE APP

a. Place your phone next to your blood pressure monitor.
b. Start the iHealth MyVitals App on your smartphone (ensure that your Bluetooth is activated in your settings).
c. Press the "M" (Memory) button on the monitor. The Bluetooth symbol will be displayed when the monitor is successfully connected to the iHealth MyVitals app.
d. After synchronizing the stored results with the app, all stored results on the monitor will be removed automatically.

Note:
• The blood pressure monitor can not be connected to the iHealth MyVitals app when the battery is low or the monitor is taking measurements.

9. TECHNICAL ALARM DESCRIPTION

The monitor will show 'HI' or 'Lo' as a technical alarm on LCD without 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 a 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.

10. TROUBLESHOOTING

Problem	Explanation	Solution
LCD shows a 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"	Fail to detect systolic pressure.	
LCD shows "Er 2"	Fail to detect diastolic pressure.	
LCD shows "Er 3"	The pneumatic system is blocked, or the cuff is too tight during inflation.	Apply the cuff correctly and try again.
LCD shows "Er 4"	Pneumatic system leakage or the 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 for five minutes, and then reinstall the batteries.

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

MAINTENANCE

1. ⚠ Do not drop the monitor or subject it to strong impacts.
2. ⚠ Avoid high temperatures 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. Please remove the batteries if you do not use the monitor for a long time.
6. It is recommended that the performance of this monitor be checked every two years.
7. Please clean the 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, part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel in repairing those parts of equipment which are designated by the manufacturer as repairable.
9. If the cuff is used in a hospital or a clinic, it is recommended to disinfect it twice a week. Wipe the cuff's inner side (the side that contacts skin) with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then airdry 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 closure cycles.
11. ⚠ No servicing/maintenance while the monitor is in use.
12. The monitor requires 6 hours to warm from the minimum storage temperature between uses until it is ready for its INTENDED USE when the ambient temperature is 20 °C.
13. The monitor requires 6 hours to cool from the maximum storage temperature between uses until it is ready for its INTENDED USE when the ambient temperature is 20 °C.

SPECIFICATIONS

Product name: iHealth Track Connected Blood Pressure Monitor
Model: KN-550BT
Classification: Internally powered, Type BF applied part; IP21, No AP or APG; Continuous operation
Device Dimensions: 38.6"x 38.6"x 18.1"(9.8 × 9.8 × 4.6cm) (not including the cuff)
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 5.2
Frequency Band: 2.400-2.4835 GHz
Precision of the displayed values: 1mmHg
Measuring accuracy: Pressure: ±3mmHg, Pulse rate: ±5%
Operation conditions: 50°F~104°F(10°C~40°C), ≤85% RH, 80~105kPa
Storage/Transport condition: -4°F~122°F(-20°C~50°C), ≤85% RH, 80~105kPa
Battery life: Approximately 300 measurements
This blood pressure measurement system includes accessories: A pump, valve, cuff, and sensor.
Note: These specifications are subject to change without notice.

This device bears the CE conformity mark. The quality of this wireless device has been verified and conforms to the provisions of the IEC 60601-1Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 (Medical electrical equipment-Part 1: General requirements for safety); IEC60601-1-2:2014/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); IEC80601-2-30:2018/EN IEC80601-2-30:2019 (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 iHealth Track Blood Pressure Monitor and other devices and advice regarding avoiding such interference, please visit www.ihealthlabs.eu/support/electromagnetic. It is suggested that the Wireless Blood Pressure Monitor should be operated at least 30 cm away from electric or wireless devices (e.g., routers, microwave ovens, etc.).

EXPLANATION OF SYMBOLS ON UNIT


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


WARNING


TYPE BF APPLIED PARTS (The cuff is type BF applied part)

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.)

MANUFACTURER

Symbol for "DATE OF MANUFACTURE"

MR Unsafe

Recyclable identification

SN SERIAL NUMBER

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

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WARRANTY INFORMATION

iHealth Labs, Inc. ("iHealth") warrants the iHealth hardware (the "Product"), and only the Product, against defects in materials and artistry under regular use for one year (US) or two years (EU) from the date of purchase by the original purchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by law, these are the sole and exclusive remedies.

This warranty does not apply: (a) to consumable parts, such as the cuff or the battery, that diminish over time unless failure has occurred due to a defect in materials or quality; (b) to cosmetic damage, including but not limited to scratches, dents; (c) to damage caused by accident, abuse, misuse, contact with liquid; (d) to damage caused by operating the iHealth product outside the user manual, the technical specifications or other iHealth product published guidelines; (e) to damage caused by service performed by anyone who is not a representative of iHealth or one of its representatives.

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:

This device may not cause harmful interference, and 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, under 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 following 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 to 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 license-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 applies to the equipment and system requirements to receive radio frequency energy for work; Bluetooth receives a bandwidth of 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

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	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

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