

iHealth[®] Track

Fully Automatic iHealth Track Connected
Arm Blood Pressure Monitor
USER 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(22cm-42cm)
- 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



Memory Indicator



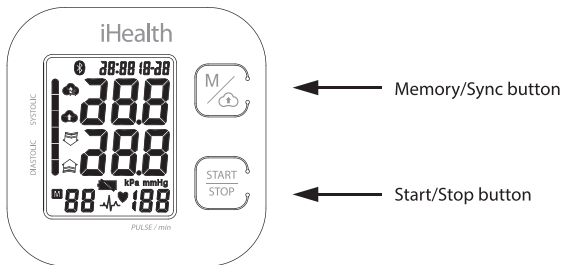
Release Air Symbol

 Synchronization Symbol

 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 Store or on GooglePlay 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 www.ihealthlabs.eu and log in

using the same account as you used with your App.

The iHeath Track Blood Pressure Monitor is designed to be used with *Bluetooth* 4.0 Apple devices and selected *Bluetooth* 4.0 Android smartphones. Please note that the compatible devices are subject to change. For the latest compatibility list visit www.ihealthlabs.eu/support.

HOW TO USE YOUR BLOOD PRESSURE MONITOR


1. BATTERIES

- a. Open the battery cover at the back of the device.
- b. Load four “AAA” size batteries. Please pay attention to polarity.
- c. 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.



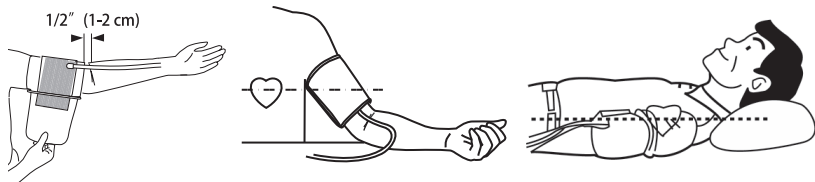
 *The monitor, the batteries and the cuff must be disposed of according to local regulations at the end of their usage.*

2. HOW TO PLACE THE CUFF ON YOUR ARM

The iHeath Track Blood Pressure Monitor has a universal size cuff. This means that it will fit any arm with a circumference between 22 and 42cm. If your arm is too large to fit in this cuff, you might consider using a wrist blood pressure monitor.

- a. Place the cuff tube downwards, around a bare arm about 2cm above the elbow joint.

b. Sit with your feet flat on the floor without crossing your legs. While seated, place your palm upside 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 palm-side 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.

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 that the cuff fits your arm (22 – 42cm), simply insert the cuff connector into the socket 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 readjust 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 colours (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.

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 the 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

6. MEMORIES

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 display, press the “M” button, the newest measurement will display. Press “M” button again to review the next measurement. During display the memories, keep on pressing button “M” for three seconds, all results in the current memory bank will be deleted.

If no result stored, LCD will show zero.

The monitor will automatically switch off after one minute to save the 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 Store (for iOS devices) or on GooglePlay Store (for Android). You then need to create your own iHealth account on 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 blood pressure monitor. The number of readings in the memory will be displayed. After a few seconds the iHealth Track Blood Pressure Monitor will automatically start synching the readings to the iHealth MyVitals App. While it is synchronizing you will see the readings numbers gradually come down on the blood pressure monitor, until they reach zero. When zero is displayed on your monitor, it means that all the readings have been synchronized and that you can now view all your data in the "List" of the iHealth MyVitals App.
4. If no result stored, the number of readings in the memory will be displayed zero.

8. TROUBLESHOOTING

Problem	Explanation	Solution
LCD shows low battery symbol 	Low Battery	Change all the batteries
LCD shows "Er 0"	Pressure system 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"	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 is still there, please contact your local iHealth distributor
LCD shows "Er 6"	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows "Er 7"	EEPROM accessing error	
LCD shows "Er 8"	Device parameter checking error	
LCD shows "Er A"	Pressure sensor parameter error	
No response when you press button or install batteries	Incorrect operation or strong electromagnetic interference.	Take out the batteries, wait five minutes and then reinstall batteries

Please visit the support section of the www.ihealthlabs.eu website to see our comprehensive Frequently Asked Questions on blood pressure.

9. GENERAL SAFETY AND PRECAUTIONS

1. Carefully read the user guide before operating the device.
2. Consult your physician for any of the following situations:
 - a) The application of the cuff over a wound or inflamed area.
 - b) The application of the cuff on the arm on the side of a mastectomy.
 - c) Simultaneous use with other medical monitoring equipment on the same limb.
 - d) The application of the cuff on any limb with intravascular access or therapy, or an arteriovenous (A-V) shunt.
 - e) The blood circulation of the user needs to be checked.
3. Do not use this product in a moving vehicle as this may result in inaccurate measurements.
4. The IHB symbol will be displayed under 2 sets of circumstances:
 - a) The coefficient of variation (CV) of pulse period >25%.
 - b) The difference of adjacent pulse period is ≥ 0.14 s and more than 53% of the total number of pulses readings falls within this definition.
5. Please do not use any cuff other than that supplied by the manufacturer as this may result in inaccurate measurements.
6. 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 preclampsia.

⚠ 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.

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

11. AFTERSALES AND WARRANTEE

This device has been developed by iHealth together with a team of medical specialists and engineers. We have taken the utmost care to manufacture a device that is user friendly and clinically accurate. It has been validated against the exacting standard of the ESH (European Society of Hypertension) and as such can be used by a medical professional in clinical practice. The iHealth Track Blood Pressure Monitor carries a two-year warrantee according to European legislation.

If you have any questions regarding the aftersales or usage of the product, please visit www.ihealthlabs.eu 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.eu.

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 "Type BF Applied Parts" (cuff only)



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 "KEEP DRY"



Symbol for "Manufacturer"



Symbol for "DATE OF MANUFACTURE"



Symbol for "EUROPEAN REPRESENTATIVE"



Symbol for "SERIAL NUMBER"

CE 0197 CE conformity mark



iHealthLabs Europe SAS
36 Rue De Ponthieu, 75008, Paris, France
support@ihealthlabs.eu www.ihealthlabs.eu



ANDON HEALTH CO., LTD

Add:No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin 300190, China.
Tel: 86-22-60526161

iHealth is a trademark of iHealth Labs, Inc.

The *Bluetooth*[®] word mark and logos are registered trademarks owned by *Bluetooth SIG*, Inc. and any use of such marks by iHealth Labs, Inc. is under license.

Other trademarks and trade names are those of their respective owners.

13. SPECIFICATIONS

Product name: iHeath Track Blood Pressure Monitor

Model: KN-550BT

Classification: Internally powered, type BF applied part; IP20, No AP or APG; Continuous operation

Machine size: 98 × 98 × 46mm

Cuff circumference: 22 - 42cm

Weight: 348g (batteries and cuff included)

Measuring method: oscillometric method, automatic inflation and measurement

Memories: 99

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 Class 2

Frequency Band: 2.400-2.4835 GHz

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

Environmental temperature for operation: 10 ~ 40°C

Environmental humidity for operation: ≤ 85 %

Environmental temperature for storage: -20 ~ 50°C

Environmental humidity for storage: ≤ 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.

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); IEC80601-2-30:2009+AMD1: 2013/EN 80601-2-30:2010/A1: 2015 (Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers). ISO81060-2: 2013(Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type).

Hereby, [ANDON HEALTH CO., LTD] declares that the radio equipment type [KN-550BT] is in compliance with Directive 2014/53/EU.

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.).

The full text of the EU declaration of conformity is available at the following internet address:
www.ihealthlabs.eu

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, ± 5 kHz 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		