

withings

Reviewer's guide

BPM Core





CLINICALLY APPROVED

BPM Core

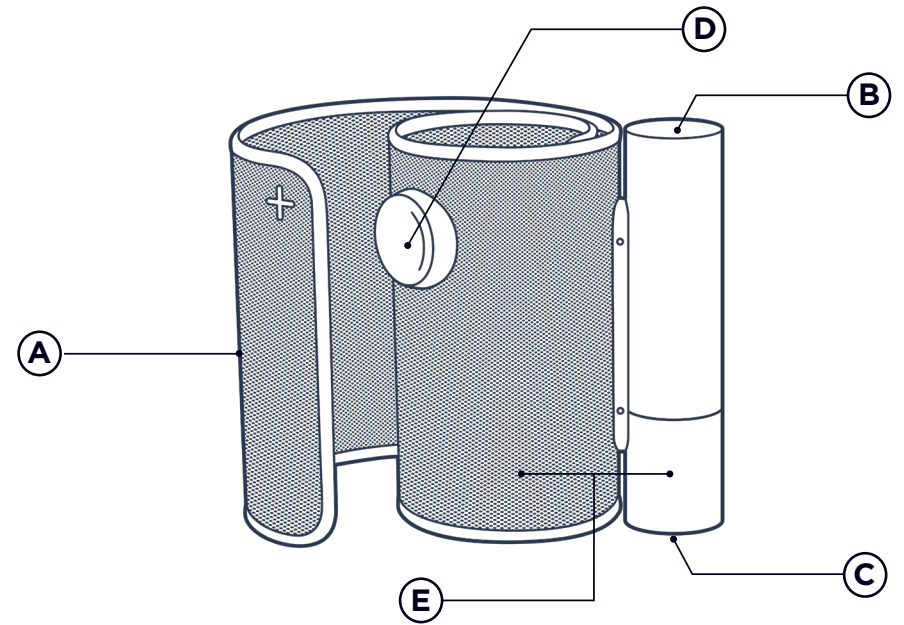
Smart blood pressure monitor with ECG & digital stethoscope

- Blood pressure monitor
Systolic and diastolic blood pressure plus heart rate
- Electrocardiogram
ECG record and atrial fibrillation detection
- Digital stethoscope
Detect valvular heart diseases
- Medically accurate
FDA cleared / Compliant with European medical device standards
- Immediate feedback
Immediate results on device & in app
- Automatic smartphone sync
All results available instantly via the free Health Mate app (iOS & Android™)
- Share with your doctor
Save and share data with your healthcare provider
- Rechargeable battery
Lasts up to 6 months
- Unlimited data storage

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1. Overview



(A) Cuff

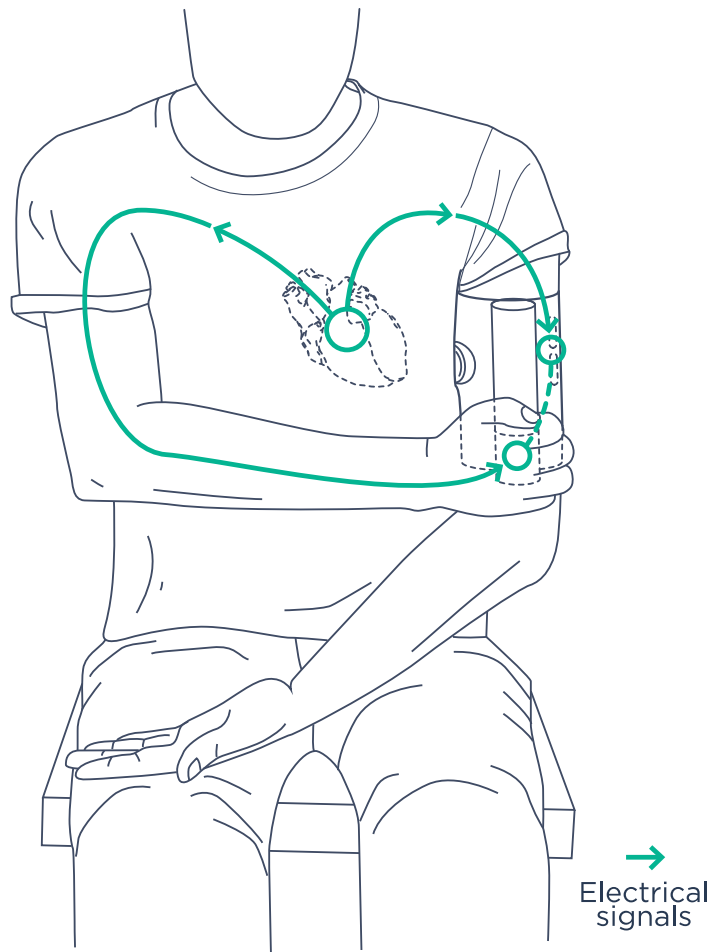
(B) Button

(C) USB plug

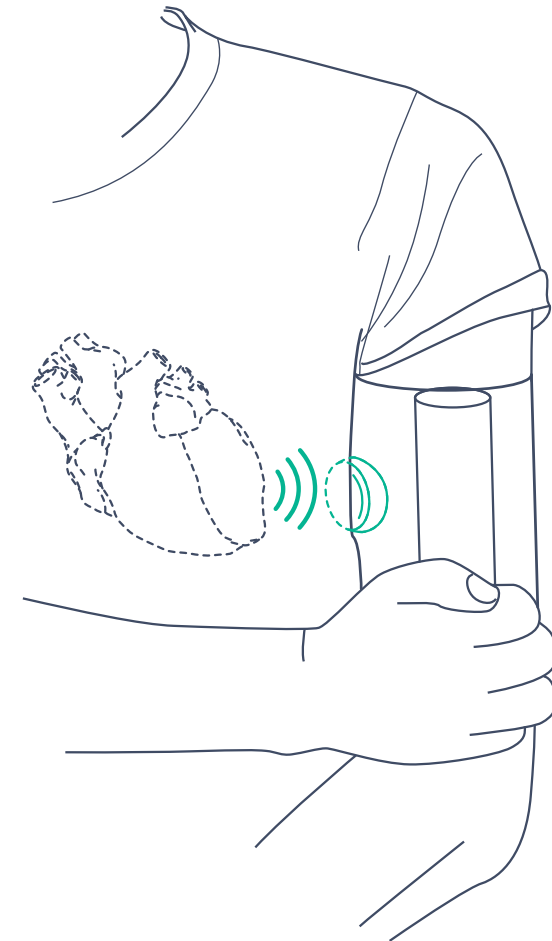
(D) Digital stethoscope

(E) Electrodes

There are three electrodes, two located inside the cuff and one on the metal tube you hold during the measurement. By placing your hand on the metal tube of the device during the measurement, you will record an ECG (electrocardiogram) and help detect any signs of atrial fibrillation (AFib).



The integrated digital stethoscope is placed against your chest during the measurement to listen to and interpret heart sounds. This can help detect signs of valvular heart disease (VHD).



2. Get started

#1 WORLDWIDE

WITHINGS INVENTED THE FIRST BLOOD
PRESSURE MONITOR WITH AN ECG &
A DIGITAL STETHOSCOPE

BPM Core is the world's first smart blood pressure monitor designed to monitor and detect two cardiovascular diseases that are more common among people who have high blood pressure. BPM Core has been created to enhance heart health prevention and detection, right from the comfort of home.

This 3-in-one device helps precisely monitor blood pressure & heart rate, detect atrial fibrillation (AFib) via the ECG, and detect the most prevalent forms of valvular heart disease (VHD) via the integrated digital stethoscope.

Installation

Visit go.withings.com from your smartphone or tablet, and follow the instructions to install the Health Mate app. In the app, follow the instructions to install Withings BPM Core.

The Bluetooth on your phone needs to be enabled so it can detect the device.

Once the device is paired with your phone, you will be asked to select a Wi-Fi network. Once it's connected to your Wi-Fi network, BPM Core will be able to automatically synchronize your data, without having to enable your Bluetooth on your phone.

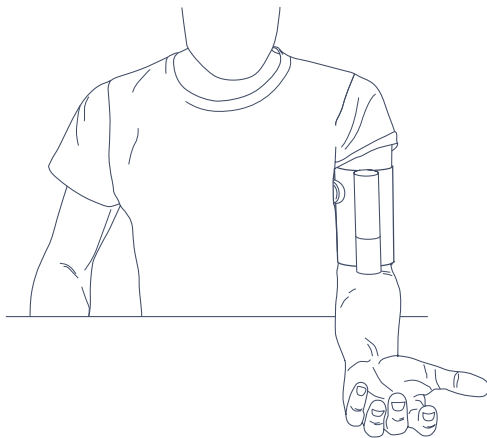
If you don't have a Wi-Fi connection, you can select the Bluetooth-only option, but the data will only be synced if you have your phone on you, via Bluetooth.



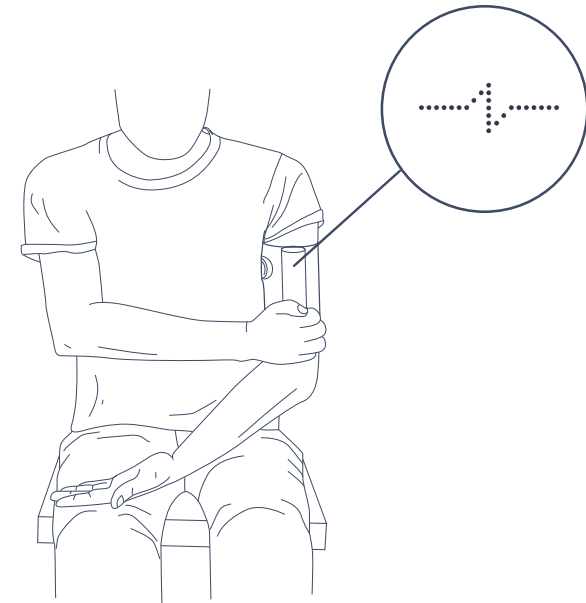
Taking a measurement

BPM Core is a medical device. To ensure the accuracy of the measurement, you need to follow certain guidelines:

- Rest 5 minutes before the measurement.
- Sit down in a comfortable position, legs uncrossed, feet flat on the floor, arm and back supported.
- Use the product on the left upper arm with the tube positioned against your inner arm.
- Do not speak or move during the measurement.
- You can wear one layer of clothes but it should not cover your left arm. The electrodes should be in contact with the skin.
- The stethoscope should be placed next to your chest and electrodes in contact with the skin of your left arm.
- Take the measurement in a calm and quiet area.



During the measurement, when the product displays the illustrated pictogram on the screen, you need to place your hand on the metal tube to record the ECG.



Please refer to the instruction manual for additional information on how to correctly take a measurement.

3. Understanding your results

a. Results on the LED screen

After each measurement, you'll see your results instantly on the LED screen of the device.

SYS refers to systolic blood pressure, when the heart contracts and ejects blood into the arteries. DIA refers to diastolic blood pressure, when the heart relaxes. HR means heart rate, the speed at which the heart beats.

The results come with color-coded feedback based on the recommendations for hypertension of the European Society of Hypertension.

You'll also see "AFib: yes / no," to see at a glance if BPM Core has detected signs of atrial fibrillation or not. More detailed information is available in the app.

If several people use your device, you can attribute the measurement to a specific user by sliding the light trail on the device until you find the right name and then click on the button on the upper part of the tube to validate the attribution. Note that if you select "Guest," results won't be sent to the app.



Did you know?

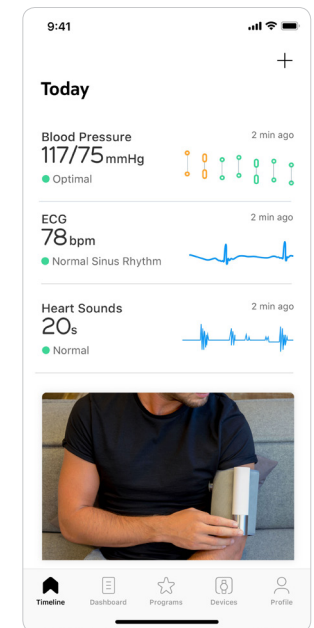
Atrial fibrillation is the most common form of heart rhythm disorder. It's estimated that 1 in 4 middle-aged adults will develop it. AFib can be detected via an electrocardiogram (ECG).

A valvular heart disease is an often underdiagnosed cardiac condition prevalent amongst people with high blood pressure. A VHD can be detected by listening and interpreting heart sounds, thanks to a stethoscope.

b. Results in the Health Mate app

You will find your full data history in the Health Mate app.

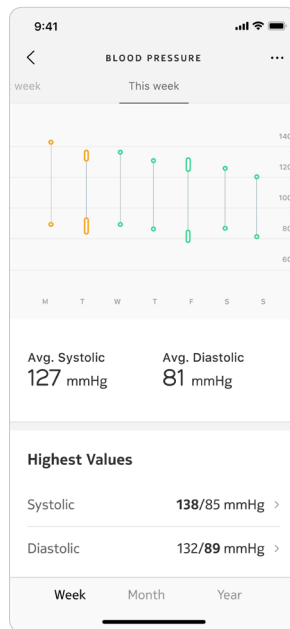
The device synchronizes via Wi-Fi or Bluetooth. If you set up with Wi-Fi connection, there's no need to have your smartphone next to you during or after the measurement, as data is automatically synchronized via your home Wi-Fi network. When you open the app after a measurement, you'll see your blood pressure, ECG and heart sounds results on your timeline.



Blood pressure results

Tap on Blood Pressure to see your measurement history in more detail.

Like the results you get on the screen, the results on the app are color-coded to make them easier to understand.



BPM Core is compliant with European medical device standards, meaning that your doctor can use and interpret the measurements provided by the device to help better manage hypertension and check the efficacy of treatments.

You can easily share your blood pressure history with your doctor by tapping on the three dots on the upper part of your screen. You can then enter your doctor's email address to send them an Excel file by choosing the period of measurements you want to send, even if you want to send a periodic reminder.

The screenshot shows the 'Share with my doctor' screen. At the top, there's a status bar with the time 09:47 and signal indicators. Below the title, there's a 'Recipient' field and an 'Email' field. Underneath, there are two tabs: 'Extended' and 'Over the last 3 months'. A blue 'Confirm' button is located below the tabs. At the bottom, there's a 'Periodical sending reminder' toggle switch, which is currently turned off.

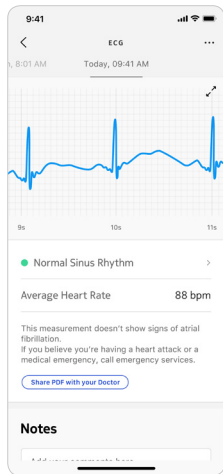
ECG measurement

Tap on the ECG signal to see more details. You can easily replay the signal by clicking on the play button.

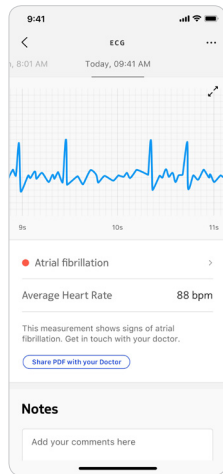
With each heartbeat, an electrical wave travels through your heart. It is this wave that causes your heart to squeeze and pump blood. The electrocardiogram (ECG or EKG) shows the precise time it takes for that process to happen.

ECGs can detect a range of conditions, but Withings BPM Core focuses on atrial fibrillation.

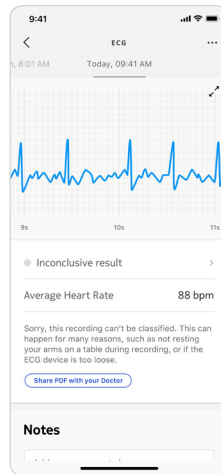
Below are the results you may see:



Normal Sinus
Rhythm



Atrial
fibrillation



Inconclusive

Normal Sinus Rhythm

A sinus rhythm means your heart is beating in a uniform pattern.

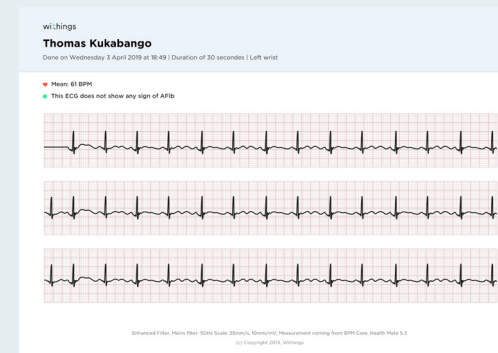
Atrial fibrillation

Atrial fibrillation occurs when the two upper chambers of the heart move chaotically instead of pumping regularly. This creates a very jumpy baseline on the ECG graph.

Inconclusive

An inconclusive result means the recording can't be classified. This can happen for many reasons, such as not resting your arms on a table during a recording, or perhaps your device was too loose on your arm. Certain physiological conditions may prevent a small percentage of users from creating enough signal to produce a good recording.

You can easily share your ECG signals with your doctor by tapping on "Share PDF with your doctor." It will then generate a PDF with your latest ECG that you will be able to share with your healthcare provider. AFib is underdiagnosed, as episodes can occur outside of visits to the doctor. Sharing your ECG records with your healthcare provider can help detect it sooner and consequently better prevent the disease progression.



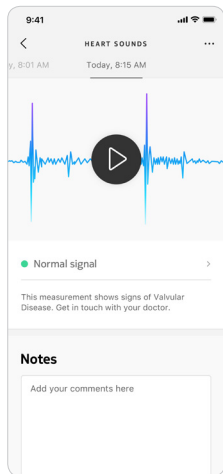
Heart sounds

Tap on Heart Sounds to have more details on the recording of your heart captured by the digital stethoscope. You can also replay the recording and hear your heart sounds.

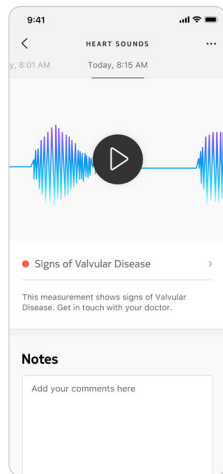
Note that after installing your BPM Core, you will need up to five valid measurements before you can access the heart sounds graph.

With this recording, the algorithm interprets your heart sounds and detect potential signs of a valvular heart disease (VHD). BPM Core helps detect the three most prevalent VHDs.

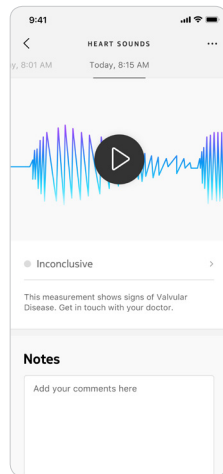
Here are the results you may have:



Normal
heart
sounds



Signs
of valvular
heart disease



Inconclusive

Normal heart sounds

No sign of VHD is detected.

Signs of valvular heart disease

The measurement shows signs of a VHD. It's then recommended you get in touch with your doctor.

Inconclusive

An inconclusive result means the recording can't be classified. This can happen for many reasons such as not resting your arms on a table during the recording, or if your device is too loose on your arm. Certain physiological conditions may prevent a small percentage of users from creating enough signals to produce a good recording.

4. Cheat sheet

BPM Core

Smart blood pressure monitor with ECG & digital stethoscope

BPM Core is the world's first blood pressure monitor that helps monitor and detect frequent cardiovascular diseases among people suffering from high blood pressure: atrial fibrillation (AFib) via the ECG and the most prevalent forms of valvular heart disease (VHD) via the integrated digital stethoscope. See your results directly on the device with immediate color-coded feedback. BPM Core synchronizes seamlessly via Wi-Fi & Bluetooth to the free Health Mate app, where you can see all your data history and share it with your doctor.

- Systolic and diastolic blood pressure, heart rate
- Electrocardiogram: atrial fibrillation detection
- Digital stethoscope: listens to heart sounds for signs of valvular heart diseases
- Medically accurate: CE medical approved
- Wi-Fi and Bluetooth® data sync
- Easily share reports with your doctor

Diseases that can be detected and monitored

Hypertension

1 in 3 adults have high blood pressure — and many don't know it. Hypertension is the leading preventable cause of premature mortality worldwide. The American Heart Association and the European Society of Hypertension recommend home blood pressure monitoring for a better management of hypertension.

Atrial fibrillation detection via ECG

1 in 4 middle-aged adults will develop atrial fibrillation. Atrial fibrillation (AFib) is the most common form of arrhythmia and can lead to heart failure, fatigue and shortness of breath. AFib is also a major risk for stroke. AFib is underdiagnosed as episodes can occur outside of doctor's visits. AFib is paroxysmal at the beginning and can become permanent over time.

Valvular disease detection via digital stethoscope

Valvular heart disease (VHD) is characterized by damage to the heart valves that may require surgical intervention to avoid heart failure. VHD is prevalent among people with hypertension and is often underdiagnosed.

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