

A close-up photograph of a man's arm and shoulder. He is wearing a white t-shirt. A grey fabric blood pressure cuff is wrapped around his upper arm. The cuff has a white plastic sensor unit attached to it. The sensor unit is cylindrical and has the brand name 'withings' printed vertically on its silver-colored base. The background is a solid light blue color.

The science behind BPM Core

Smart blood pressure monitor

with ECG & digital stethoscope

CLINICALLY APPROVED

withings

Heart disease: a silent killer

Heart disease is the leading cause of death among both men and women, according to the Centers for Disease Control. Approximately 610,000 Americans die of heart disease every year. Worldwide, the statistics are startling—17.9 million people die each year from cardiovascular disease, according to the World Health Organization. Early detection of heart disease can be crucial. Because some conditions can be asymptomatic or paroxysmal during their early stages, they may not be detected during infrequent physician or hospital visits.

BPM Core is a smart blood-pressure monitor with electrocardiogram (ECG) and a digital stethoscope designed to help users monitor and prevent heart disease. In a medical setting, several different devices are used to monitor blood pressure, detect AFib and listen for signs of VHD—but with BPM Core, users can monitor blood pressure at home in one convenient 3-in-1 device and then share the results with their doctors in the Health Mate app.

The award-winning BPM Core looks like a traditional arm cuff, but has advanced built-in medical sensors, including two stainless-steel electrodes located inside the cuff and on the tube, as well as a silicone membrane housing a digital stethoscope.

BPM Core may help to detect the following conditions:

- [Hypertension \(measured via systolic and diastolic blood pressure\)](#) is when the pressure of the blood being pumped through arteries is higher than it should be. Hypertension affects 1 in 3 adults. It is a major cause of strokes and plays a significant role in heart attacks.
- [Atrial fibrillation \(AFib\)](#) is the most prevalent type of arrhythmia, affecting the electrical conduction that controls the heart muscle. AFib has an average prevalence between 0.4% and 2%, depending on the study. It rises with age, from 2.3% in those older than 40 years to 5.9% in those older than 65 years.
- [Valvular heart disease \(VHD\)](#) affects how the valves function to regulate blood flow in and out of the heart. BPM Core notifies you if you're at risk for any of the three most prevalent valvular heart diseases: aortic stenosis, mitral regurgitation and aortic regurgitation. Valvular heart disease has an average prevalence of 2.5% but rises sharply with age, from 0.3% for people age 18 to 44 years to 10% for people over 65.

We've included some information on how BPM Core may help detect and monitor factors leading to these conditions.

Hypertension

The definition of high blood pressure varies, depending on whether it is recorded at home or in the doctor's office. When blood pressure is taken at home, it is considered normal when the average measurement is less than 130/80 mmHg. When it is measured by a doctor or pharmacist, blood pressure is considered normal when it is below 140/90 mmHg. When it exceeds these values, the person has hypertension.

Hypertension is one of the most common chronic diseases in the world and is considered a major cardiovascular risk factor. In addition, it causes anomalies and stiffening of the arterial walls due to the permanent mechanical pressure exerted on them. Chronic hypertension increases the risk of stroke, coronary heart disease, heart failure, kidney failure and cognitive disorders.

Classifications

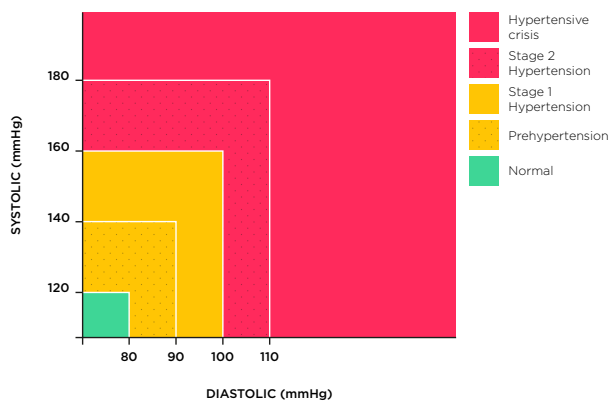


Figure 1: Classification of blood pressure levels from the European Society of Hypertension and the European Society of Cardiology

Symptoms

Signs of hypertension may include a constant or severe headache in the morning, dizziness, blurred vision, palpitations, sweating, and even nosebleeds.

Disease progression and consequences

High blood pressure can cause damage your body for years before symptoms develop. If left undetected, high blood pressure can lead to heart failure, stroke, kidney disease, vision loss, sexual dysfunction, and other conditions.

Diagnosis

High blood pressure is often “silent”, with no symptoms; therefore, many people may have hypertension without knowing it. Monitoring your blood pressure may enable you and your physician to detect hypertension before the onset of complications. Self-measurement of blood pressure at home can be a useful tool for the screening and monitoring of high blood pressure, and information provided by BPM Core can be shared with your healthcare provider.

Treatment

In addition to drug therapy, certain lifestyle changes can help reduce blood pressure. People with hypertension may want to reduce their intake of salt, alcohol, and high-fat foods; lose weight if they are overweight; stop smoking; increase fruit and vegetable consumption; and exercise regularly.

How does BPM Core work?

Blood pressure is indicated by two numbers. The first corresponds to systole, when the heart contracts and ejects blood into the arteries. The second corresponds to diastole, when the heart relaxes. The unit of measurement of blood pressure is the millimeter of mercury (mmHg).

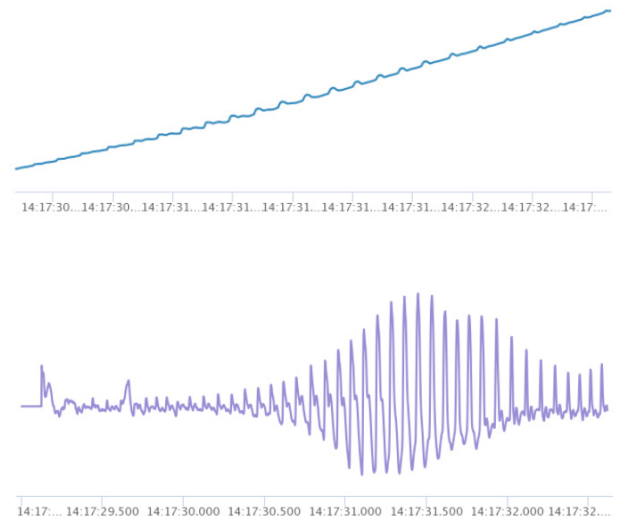


Figure 2: Raw blood pressure signal and blood pressure signal without the baseline obtained with BPM Core

The self-inflating cuff of BPM Core accurately tracks and monitors systolic blood pressure, diastolic blood pressure and heart rate measurements, and provides results instantly on the device via an LED matrix display. The display also provides color-coded feedback glowing green for normal, orange for moderate and red for high blood pressure. Data is also sent to the Health Mate app via Bluetooth or WiFi.

Atrial fibrillation

Atrial fibrillation (AFib) is a type of arrhythmia, or an irregular heartbeat.

Normally, electrical signals in the sinus node of the right atrium contract the heart so it pumps blood. In atrial fibrillation, the electrical impulses are disorganized and scattered throughout both atria. As a result, the heart beats too quickly and irregularly, which may lead to decreased blood flow and oxygen throughout the body.

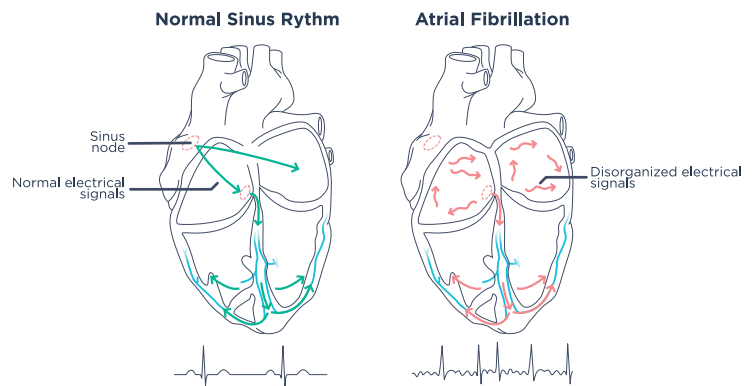


Figure 3: Electrical activity of the heart with and without atrial fibrillation

Stages

AFib has three stages:

- **Paroxysmal:** In this first stage, AFib comes and goes, and stops on its own.
- **Persistent:** In the second stage, AFib progresses. It lasts more than a week and can become permanent.
- **Permanent:** In the third and most severe stage, the condition progresses until the heart's normal rhythm cannot be restored.

Symptoms

AFib is often asymptomatic. AFib may be brief (paroxysmal) with symptoms that come and go. Heart palpitations are the most common, and fatigue and weakness may also occur.

Diagnosis

The only way to diagnose AFib is to record an ECG. This makes diagnosis difficult during the early stage of the disease, as episodes of AFib are temporary, and may not often be registered during a cardiologist's visit. To record an episode, patients can wear a Holter monitor for 24 hours or longer. Also, this disease may not be detected by a general practitioner if they do not have the ability to administer an echocardiogram.

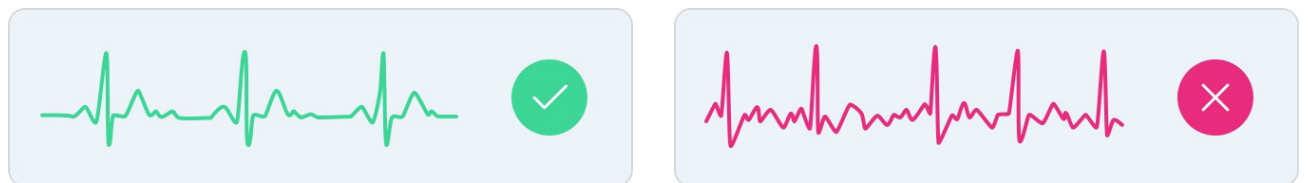


Figure 4: Normal ECG graph (green) and ECG graph showing signs of atrial fibrillation (red)

Indeed, intermittent and symptom-based monitoring shows sensitivities ranging from 31 to 71% and negative predictive values ranging from 21% to 39% to identify patients who are already known to have AFib.

The main issue with diagnosing AFib is the ability to record an episode when the disease is at its early stage (paroxysmal) or asymptomatic. BPM Core records an ECG signal of 20 seconds that can be shared with a doctor to assist with analysis, diagnosis, and treatment.

For example, if the patient feels palpitations, they can record a measurement to record an episode. Also, because an ECG signal will be recorded during each measurement, BPM Core can help to diagnose an asymptomatic AFib.

Treatment

The treatment goals for AFib are to reset the heart's rhythm, prevent blood clots, and decrease the risk of strokes. The longer a patient has AFib, the less likely it is that doctors can restore a normal heart rhythm. The recommended treatments for AFib include blood-thinning medicines that prevent blood clots or slow

down the rate at which the ventricles are beating, although an abnormal heart rhythm may continue. Most people feel better and can function well if their heart rates are well controlled.

If these treatments are not working well, doctors may also prescribe rhythm-control medicines, or use electrical cardioversion—electrical shocks on the heart that trigger a normal rhythm while the patient is sleeping.

When drugs and electrical treatments are not effective, doctors may perform an ablation to destroy the tissue in the area where the heart is misfiring.

Disease progression and consequences

The progression of the disease varies among individuals. Most of the time, the disease progresses to permanent AFib.

The risk of having a stroke is five times higher for people who have AFib. When a heart contraction is either too fast or too uneven, it doesn't completely squeeze the blood out of the atria. The blood pools and can clot. The blood clot can be pumped out of the heart to the brain and block off the blood supply to an artery in the brain, causing a stroke.

AFib can cause the heart to beat so fast that it doesn't fill up with enough blood to pump out to the body. This condition is called heart failure. Heart failure can cause fatigue and shortness of breath.

For those who have AFib, the risk of mortality is multiplied by a factor between 1.5 and 1.9.

How does BPM Core work?

BPM Core records a one-lead electrocardiogram between the left arm and the right arm for 20 seconds. In this signal, the algorithm will detect the QRS complex and analyze the time between each of them to determine whether the rhythm is normal or if the user potentially has AFib.

To record an ECG that can detect AFib, a user places the cuff on the upper arm and places the other hand on its stainless-steel sensors for 20 seconds. Heart rhythms are tracked and displayed within the Health Mate app and will show if the heart beats too quickly and irregularly.

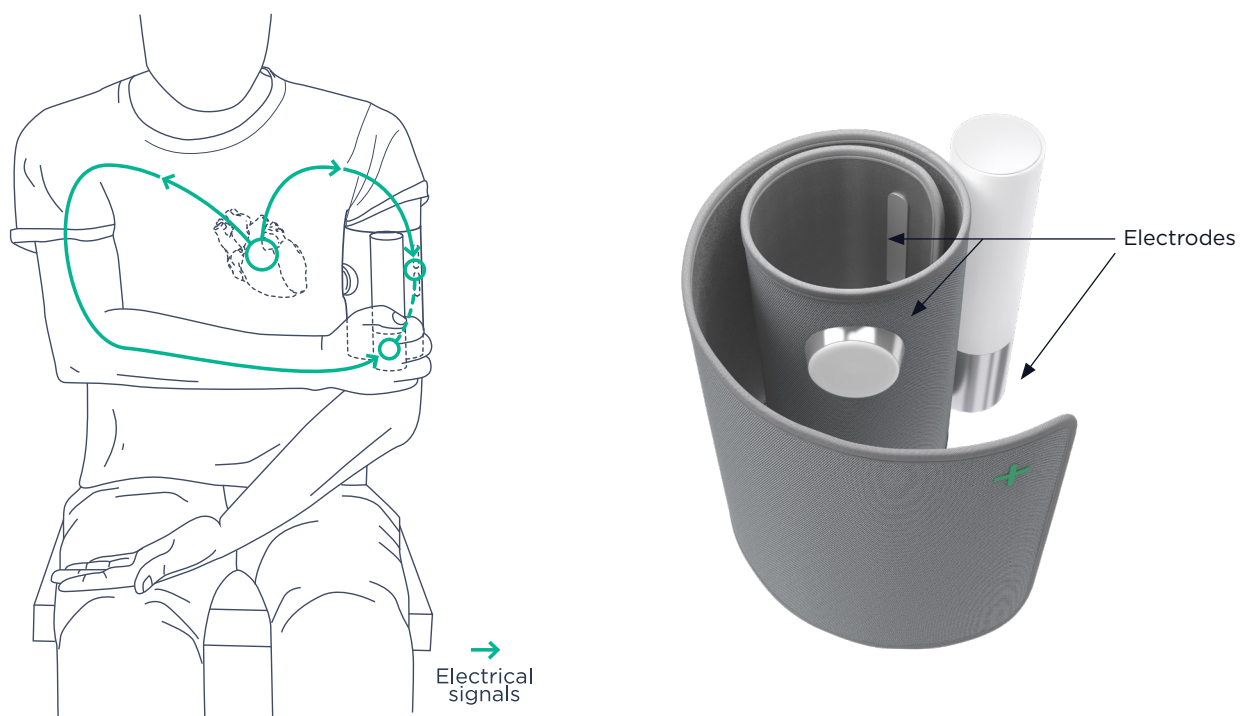


Figure 5: Illustrations of how BPM Core records an ECG signal thanks to 3 electrodes

Valvular heart disease

Valvular heart disease (VHD) is characterized by damage to or a defect in one of the four heart valves: the mitral valve, aortic valve, tricuspid valve, or pulmonary valve.

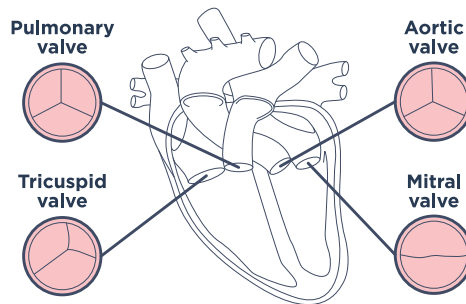


Figure 6: Illustration of the four heart valves

Normally functioning valves ensure that blood flows with proper force in the proper direction at the proper time. In valvular heart disease, the valves become too narrow and hardened (stenotic) to open fully, or are unable to close completely (insufficient).



Figure 7: Illustration showing the difference between a normal and a damaged valve

The three most prevalent valvular heart diseases are:

- aortic stenosis
- aortic regurgitation
- mitral regurgitation

Symptoms of these diseases may be detected by BPM Core.

Symptoms

The severity of the symptoms does not necessarily correlate with the severity of the valve disease. Patients may not experience any symptoms, but still have severe valve disease.

Many symptoms are similar to those associated with congestive heart failure, such as shortness of breath and wheezing after limited physical exertion and swelling of the feet, ankles, hands or abdomen.

Diagnosis

Valvular heart diseases may be asymptomatic. 51% of people older than 65 could have undetected valvular heart disease. Valvular heart disease should be detected before the myocardium is affected in order not to delay a possible surgical intervention, such as a valve replacement.

A doctor can make a first diagnosis with a stethoscope to detect heart murmurs, which can be a sign of a heart valve condition. Patients may then be directed to a cardiologist for an echocardiogram. Sound waves directed at the heart produce video images of the heart in motion. This test assesses the structure of the heart, the heart valves and the blood flow through the heart. An echocardiograph helps the practitioner to get a close look at the heart valves and how well they're working. An echocardiograph is a key instrument in assessing any type of valvular heart disease.

BPM Core detects three main valvular heart diseases: aortic stenosis, aortic regurgitation and mitral regurgitation. If there is a risk of valvular heart disease, BPM Core users will receive a notification encouraging them to visit their doctors.

Treatment

The disease's evolution must be monitored so the physician can implement surgical intervention when needed. No drug treatment can influence survival or delay surgery once symptoms of aortic and mitral valve disease appear. On the other hand, treatments can be put in place to overcome complications of valvular heart diseases, such as heart failure or atrial fibrillation.

Depending on the state of degradation of the valves, the extent of leakage or stenosis, and the impact on the heart muscle, surgical treatment may be required. Surgery is the gold-standard treatment for heart disease.

Heart valve repair is used to fix defects in the heart valve. If the valve's lesions make it impossible to repair, the valve will be replaced by a complete prosthetic valve.

Disease progression and consequences

If valvular heart disease progresses, the heart valve will become increasingly damaged.

If the valve does not open fully or close properly, it can put extra strain on your heart, making it pump harder to force the blood, and could lead to AFib or heart failure. A damaged valve is much more susceptible to infections. This sensitivity can lead to endocarditis, or an infection of the endocardium—the inner lining of the heart's chambers and valves.

How does BPM Core work?

BPM Core has an embedded digital stethoscope, positioned to the left side of the user's chest, that will capture the sound of the heart. This signal is analyzed to detect the three most prevalent heart diseases. Each of these diseases can be recognized via a characteristic pattern on the signal.

Normally functioning valves ensure that blood flows with proper force in the proper direction at the proper time in the heart. In valvular heart disease, the valves become too narrow and hardened (stenotic) to fully open, or are unable to close completely (regurgitation). To detect valvular issues, the device uses a digital stethoscope and analytical algorithm calibrated in collaboration with George Pompidou Hospital in Paris. A user places the sensor on the chest, and it records and evaluates heart performance for 20 seconds. Results are displayed on the device and within the Health Mate app, where they can also be heard.

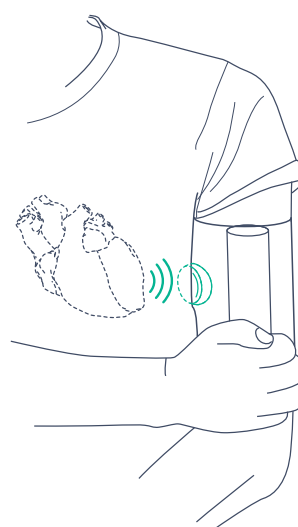


Figure 8:
Illustration of how
BPM Core captures
the sound of the heart
thanks to its digital
stethoscope

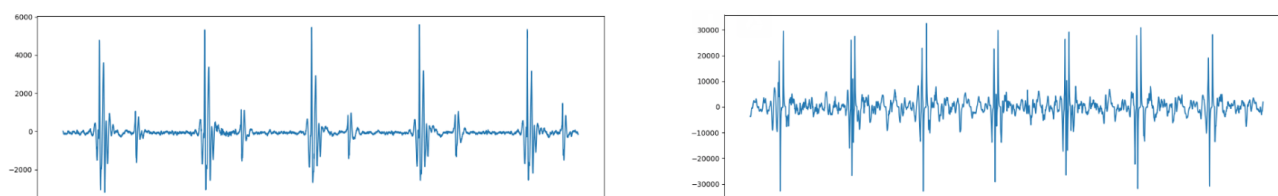


Figure 9: Heart sounds of a healthy heart and a heart with a VHD

Conclusion

With the award-winning Withings BPM Core, you can monitor the risk for several common heart conditions at home and share the results with your doctor. Learn more about how this innovative 3-in-1 device can potentially help to detect and monitor conditions at <https://www.withings.com/uk/en/bpm-core>.

References

Heart disease

Centers for Disease Control. "Heart disease facts."
<https://www.cdc.gov/heartdisease/facts.htm>

World Health Organization. "Cardiovascular diseases (CVDs)."
[https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds))

Atrial fibrillation

Jabre P, Jouven X. "Nouveautés dans la fibrillation auriculaire." Urgences 2011;
https://sofia.medicalistes.fr/spip/IMG/pdf/Nouveautes_dans_la_fibrillation_auriculaire.pdf

Go et al. "Heart Disease and Stroke Statistics—2014 Update: A Report from the American Heart Association." Circulation. 2014 Jan 21; 129(3): e28–e292;
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5408159/>

Feinberg WM et al. "Prevalence, age distribution, and gender of patients with atrial fibrillation. Analysis and implications." Arch Intern Med. 1995 Mar 13;155(5):469–73.
<https://www.ncbi.nlm.nih.gov/pubmed/7864703>

Harris K, Edwards D, Mant J. "How can we best detect atrial fibrillation?" J R Coll Physicians Edinb. 2012;42 Suppl 18:5–22. doi: 10.4997/JRCPE.2012.S02.
<https://www.ncbi.nlm.nih.gov/pubmed/22518390>

Tieleman RG et al. "Validation and clinical use of a novel diagnostic device for screening of atrial fibrillation." Europace. 2014 Sep;16(9):1291–5. doi: 10.1093/europace/euu057. Epub 2014 May 13.
<https://www.ncbi.nlm.nih.gov/pubmed/24825766>

Camm AJ et al. "2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association." Eur Heart J. 2012 Nov;33(21):2719–47. doi: 10.1093/eurheartj/ehs253. Epub 2012 Aug 24.
<https://www.ncbi.nlm.nih.gov/pubmed/22922413>

Le Heuzey JY et al. "La fibrillation atriale: données démographiques." <http://www.realites-cardiologiques.com/wp-content/uploads/sites/2/2010/03/10.pdf>

Terrier J, Carballo S. "Stratégies de dépistage de la fibrillation auriculaire." Rev Med Suisse 2015; volume 11. 1892–1898.
<https://www.revmed.ch/RMS/2015/RMS-N-490/Strategies-de-depistage-de-la-fibrillation-auriculaire>

Valvular heart disease

Lung B, Vahanian A. "Epidemiology of Acquired Valvular Heart Disease." Canadian Journal of Cardiology, 2014 Sep., 30(9), 962–970.
<https://www.sciencedirect.com/science/article/pii/S0828282X14001688>

D'Arcy J et al. "Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study." European Heart Journal, Volume 37, Issue 47, 14 December 2016, Pages 3515–3522.
<https://academic.oup.com/eurheartj/article/37/47/3515/2844994>

La Fédération Française de Cardiologie.
"Les valvulopathies, les traitements."
<https://www.fedecardio.org/Les-maladies-cardio-vasculaires/Les-traitements-des-maladies-cardio-vasculaires/les-valvulopathies-les-traitements>

Centre Cardio-Thoracique de Monaco.
"Les maladies valvulaires: Maladies, diagnostic et traitements."
<http://www.ccm.mc/pdf/MaladiesValvulaires.pdf>

withings