

## ECG Monitor Instructions for Use



### Withings

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#### 1. INDICATIONS FOR USE

ECG Monitor is medical device composed of the ECG-SW1 software and the dedicated hardware (ECG measurement and transmission) of Withings Move ECG. It is intended to record a single channel electrocardiogram (ECG) similar to a Lead I ECG. ECG-SW1 detects the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform.

The data are displayed for informational use only. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.

The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

It is not recommended for users with other known arrhythmias. ECG Monitor is intended to be used on hemodynamically stable subjects.

ECG Monitor is not intended for use by people under 22 years old. It is not intended for use by people with a pacemaker or other implanted electronic device.

#### 2. USING THE ECG MONITOR

##### a. Set-Up

- Withings Move ECG is a connected watch, distributed without ECG function
- ECG Monitor is activated during the Association of ECG-SW1 with Move ECG
- ECG Monitor is only available for Withings Move ECG, paired with a smartphone with iOS 10 or later, or Android 6 or later.

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### b. On-boarding

- Open Withings Health Mate app.
- In the timeline tab, tap “+”, then select “Electrocardiogram (ECG)”
- Follow the onscreen instructions.
- You may exit on-boarding at any time by pressing “Cancel”.

### c. Recording an ECG

- Make sure your Move ECG is snug on the wrist you selected in Devices > Move ECG > More settings> Device Orientation.
- Rest your arms on a table, and hold the top electrode with your second hand (with your thumb and index for example, as shown on fig. 05-1). You do not need to press the bezel during the session.



*Fig. 5.1 - How to place second hand to get an ECG measurement?*

- The recording starts after a first vibration.
- The recording lasts for 30 seconds.
- End of measurement is confirmed by a double vibration.

### 3. ECG Analysis

- After a successful reading, you will receive one of the following classifications on your ECG Monitor:
  - Sinus Rhythm: a sinus rhythm result means the heart is beating in a uniform pattern between 50-100 BPM.
  - Atrial Fibrillation: an AFib result means the heart is beating in an irregular pattern above 50 BPM.
  - 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

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recording, or your Move ECG is too loose. Certain physiological conditions may prevent a small percentage of users from creating enough signal to produce a good recording.

- Low or High Heart Rate: A heart rate under 50 BPM or over 100 BPM affects the ECG app's ability to check for Afib and the recording is considered inconclusive.
- After an ECG recording is complete, the ECG data is analyzed to determine if it is 30-second long, and, if so, if either Sinus Rhythm or AFib is present, or if an Inconclusive result is warranted.
- The ECG recording results on a detailed display of the result in Health Mate app.
- Presence of AFib in your ECG results may represent only potential findings. If you are experiencing any symptoms or have concerns, contact your physician. If you believe you are experiencing a medical emergency, you should contact emergency services.
- A result of Sinus Rhythm means your heart rate is between 50 and 100 beats per minute (bpm) and is beating in a uniform pattern.
- Inconclusive ECG results may mean that there may have been too much artifact or noise to acquire a good signal, or you may have an arrhythmia other than AFib the app cannot classify, or your heart rate is below 50bpm or above 100bpm. A small percentage of people may have certain physiological conditions preventing the user from creating enough signal to produce a good recording. You can learn more about Inconclusive ECG results during on-boarding, by accessing educational information in the ECG area of the Health Mate app on your smartphone.
  - A heart rate can be low because of certain medications or if electrical signals are not properly conducted through the heart. Training to be an elite athlete can also lead to a low heart rate.
  - A heart rate can be high because of exercise, stress, nervousness, alcohol dehydration, infection, AFib, or other arrhythmia.
  - If you receive an Inconclusive result due to a poor recording, you might try to re-record your ECG. You can review how to take an ECG during on-boarding or by tapping on "Take a Recording" in the ECG area of the Health Mate app on your smartphone.
- All ECGs are synced to Health Mate on your Android or iOS smartphone. You may use the Health Mate app to share your ECG with a clinician.

## 4. SAFETY AND PERFORMANCE

The ECG Monitor software's ability to accurately classify an ECG recording into AFib and sinus rhythm was tested against the IEC60601-2-47\* standard and clinical datas of 267 subjects (approximately 2800 hours of ECG recordings). Rhythm classification from ECG Monitor was compared to the ECG labeled by cardiologists on the database. The ECG Monitor demonstrated 94.38% sensitivity in classifying AFib and 93.76 % specificity in classifying Sinus Rhythm in classifiable recordings.

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During this test, 5.39% of recordings were inconclusive and not classifiable as either sinus rhythm or AFib. The ECG Monitor Software correctly classified 91% inconclusive ECG labeled as inconclusive by cardiologists on the data-set. These results reflect use in a controlled environment. Real world use of the ECG Monitor may result in a greater number of strips being deemed inconclusive.

The waveform output from the software was tested in accordance with IEC60601-2-47\* standard by a beat-by-beat QRS detection. This detection reaches a score of at least 99.18% on all the datasets with the exception of NSTDB (90.86% because of the digitally added noise).

*\*IEC 60601-2-47:2012 : Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems.*

## 5. TROUBLESHOOTING

If you experience difficulties in operating your ECG Monitor, refer to the troubleshooting guide below.

Problem 4.1: I cannot get the ECG Monitor to take a reading.

Solutions:

- Make sure your wrist and your Move ECG are clean and dry. Water and sweat can cause a poor recording.
- Ensure that your Move ECG, arms, and hands remain still during recordings.
- Ensure that you have completed all of the on-boarding steps in the Health Mate app on your smartphone.

Problem 4.2: I have an inconclusive measure. It looks like the ECG measure presents a lot of artifact, noise, or interference in my recording.

Solution:

- Rest your arms on a table or in your lap while you take a recording. Try to relax and not move too much.
- Make sure your Move ECG isn't loose on your wrist. The band should be snug and the back of your Move ECG needs to be touching your wrist.
- Move away from any electronics that are plugged into an outlet to avoid electrical interference.

Problem 4.3:

The ECG waveforms appear upside down.

Solution:

- The device orientation may be set to the wrong wrist. On your smartphone, go to the Health Mate app. Tap Devices > More Settings > Device Orientation.

All data recorded during an ECG measure are saved to HealthMate app on your smartphone. If you choose to, you can share that Information by creating a PDF.

## 6. CAUTIONS

The ECG Monitor cannot check for signs of a heart attack. If you believe you're having a medical emergency, call emergency services.

DO NOT take recordings when Move ECG is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

DO NOT take recordings during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

DO NOT take recordings when Move ECG is outside of the operational temperature range (10°C - 40°C) indicated in the Move ECG user manual and humidity range of 15% to 90% relative humidity.

DO NOT use to diagnose heart-related conditions.

DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT take a recording during physical activity.

DO NOT change your medication without talking to your doctor. Not intended for use by individuals under age 22. You should talk to your doctor if your heart rate is under 50 or over 120 at rest and this is an unexpected result. Interpretations made by this software are potential findings, not a complete diagnosis of cardiac conditions. The user is not intended to interpret or take clinical action based on ECG Monitor output without consultation of a qualified healthcare professional. The waveform generated by the ECG Monitor is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.

If waveforms are shared with cardiologists, at least 2 strips should be sent/ showed for more robust analysis.

**CAUTION:** Withings does not guarantee that you are not experiencing an arrhythmia or other health conditions when the ECG Monitor labels an ECG as Sinus Rhythm. You should notify your physician if you detect possible changes in your health.

## 7. EQUIPMENT SYMBOLS



Manufacturer

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Read instructions before use.