

User Manual

Version 0.2

**Amazfit Health Watch
JHS20W2**

Anhui Huami Healthcare Co., Ltd.



Please read this instruction manual thoroughly before using the unit. Please keep for future reference.

Caution for Prescription use:

Federal law restricts this device to sale by or on the order of a physician.

1. Indications for Use

Midong Health Watch (ECG Recorder) is designed to create, record, store, transmit, and display single-channel electrocardiogram (ECG) rhythms similar to Lead I ECG. The Midong Health Watch can also display ECG rhythms and detect the presence of AF (when prescribed by a doctor or used). Midong Health Watch is for healthcare professionals, adult patients with known or suspected AF, and health-conscious adults.

Midong Health Watch is not intended for use by people under 22 years old.

The device communicates with iOS or Android App after binding. If abnormal binding and unbinding occur, please contact the manufacturer in time to confirm.

2. Product Description

Midong Health Watch is a Bluetooth-based (transmission by Bluetooth LE) ECG (electrocardiogram) event recorder that records, stores, and transfers single-channel electrocardiogram rhythms.

The device is designed to capture a user's ECG data and transmit the data via Bluetooth to an iOS or Android mobile phone, which transmits the ECG data over the network to the Cloud servers.

The device consists of wristband, Midong Health Watch, the embedded software (installed on the Midong Health Watch), mobile phone application (*Amazfit Health app* installed on the mobile phone), and charging cable. *Amazfit Health app* can store thousands of recordings on a mobile phone, and these recordings are also accessible to authorized users on Cloud servers. All ECG data is synced with the user's account on the *Amazfit Health app*. After a user has created an account on the *Amazfit Health app*, users can view real-time ECG waveforms during recording or review historical data through their *Amazfit Health app* user accounts. The data can be stored locally on the mobile phone and transmitted to the Cloud servers for analysis and assessment by qualified professionals.

A typical configuration is to record 60 seconds of ECG per event.

The device is placed on the wrist for a single-channel ECG rhythm recording.

The heart rate is for general wellness only, not for diagnostic use. Do not make any reference to diseases or conditions.

3. General Safety Precautions

- The device should not be used in the shower or bath, or any activities like swimming

that may submerge the device in water.

- Do not use the device in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- Do not take recordings in a location where the unit is exposed to strong electromagnetic forces, such as microwave ovens or X-rays.
- Do not use the device while being charged.
- Connect to a charger with 5V output voltage and avoid charging the device under the condition that the temperature is too high or too low.
- Do not overcharge or over-discharge the device. Charge the device in time when the battery power is lower than 25% and disconnect the charging cable in time after completion of charging.
- Disperse any static electricity from your body before using the device.
- Take recordings as calm as possible.
- Do not expose the device to strong shocks or vibrations, if the shell is broken, please stop using it..
- Do not disassemble, repair, or modify the device.
- Do not take a recording if the electrode sensors are dirty. Clean them with alcohol-based sanitizer before use.
- If the portion of the body where the electrode sensor is applied has too much body fat, body hair, or very dry skin, a successful recording may not be possible.
- Do not share the device with another person to avoid cross-infection
- If the device is not to be used for a long time, please fully charge the battery and recharge it every 2 months to prevent the battery from over-discharging.
- Keep the Bluetooth connection between the device and the mobile phone when recording.
- Make sure the mobile phone has sufficient memory storage.
- When APP is registered, the password should be at least 8 characters in length, and contain two or more characters of uppercase characters, lowercase characters, base 10 digits and non-alphabetic characters.
- Avoid using commonly used passwords to prevent passwords from being guessed and maliciously logged in to reveal your personal privacy data.
- Upgrade firmware and APP in a secure network environment as much as possible.
- The MAC address is the unique identification of the device. Please do not disclose the MAC address of the device to others.

4. Warnings

- This device is not designed or intended for a complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying treatment.
- This device records heart rate and heart rhythm only.
- This device does not detect or measure heart rate, heart rhythm, and heart waveform changes.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Users should always consult their physician if they notice changes in their health.

- Do not use in the presence of flammable anesthetics, drugs, or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer, or oxygen tent).
- Do not use this device during an MRI or CT scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- The device has not been tested for use on infants weighing less than 10kg. Huami does not recommend using on humans less than 10kg.
- Do not use this device with a defibrillator.
- Huami does not recommend using on individuals with a cardiac pacemaker, ICDs, or other implanted electronic devices.
- The disposal of the device and accessories follows customary electronic waste recycling procedures.
- In case of a software crash or termination, please restart the software and re-record.
- The changes in the mobile phone memory (such as plugging, unplugging, or replacing the SD card) may cause operation failure and historical data loss.
- This produce is not allowed to be used together electrosurgical instruments.
- To keep the device away from fire, do not heat it, otherwise the internal battery may explode.

5. Warning: MR-unsafe!

- This device is NOT MRI Compatible
- Do not expose the device to a magnetic resonance (MR) environment.
- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- Thermal injury and burns may occur due to the metal components of the device that can heat during
- MR scanning.
- The device may generate artifacts in the MR image.
- The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

6. Storage and Handling

Do not store the unit in:

- Locations exposed to direct sunlight.
- Locations subject to high temperatures and high humidity.
- Wet or damp locations where water may get on the unit.
- Dusty locations.
- Near fires or open flames.
- Locations exposed to intense vibration.
- Locations exposed to strong electromagnetic fields.

7. Maintenance

Cleaning and Disinfection method

- Clean the device using an alcohol-based sanitizer before each use.

- Wipe the surface of the device with a clean, soft cloth with clean water to remove the resident sanitizer, then air dry.

8. Set up the Midong Health Watch

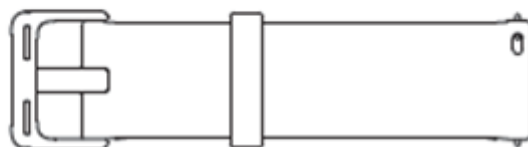
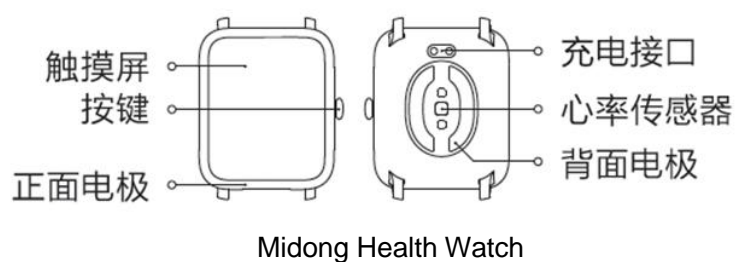
8.1 Select a mobile phone to use

The *Amazfit Health app* of the Midong Health Watch is compatible with the following systems supports Bluetooth 4.2:

- Android Operating System versions 4.4 or later
- iOS 10.0 or later

8.2 Unpack the Midong Health Watch

Remove the Midong Health Watch from the box.



腕带

8.3 Charging

Charge the ECG Recorder before the first use. As shown in the figure, attach the ECG recorder to the charging base at the end of the charging cable. Then connect the USB plug to the phone charger or a computer's USB port to charge. When charging starts, animation of the charging progress is displayed on the ECG Recorder screen.



8.4 Download *Amazfit Health app*

Use your mobile device to scan the following QR Code, depending on the system.



Download and install the *Amazfit Health app*.

8.5 Set up an account

You will use your account to access, print, and save your ECG recordings stored on the Amazfit Health app and the Cloud servers. Follow the instructions presented when opening the Amazfit Health app for the first time. You can go back later and change your information if necessary.

8.6 Connect the Midong Health Watch to mobile phone

Turn on the mobile phone Bluetooth, and connect the Midong Health Watch following the instructions presented when opening the *Amazfit Health app*. When the Midong Health Watch vibrates, and the prompt animation appears on the screen, touch the Midong Health Watch button to complete the connection of the ECG Record and the *Amazfit Health app*.

The Midong Health Watch must be less than 10 m from the mobile phone to ensure communication between devices.

8.7 Environment in which the product is intended to be used

8.7.1 The device is protected against security threats that are connected to an insecure

network environment (e.g., public WIFI) when it is logged in, upgraded, and unbound.

8.7.2 In the case of device binding, other mobile phones can not search for the device via Bluetooth. They need to be unbound before they can be found and bound by other mobile phones to ensure the security of device binding.

8.7.3 In the case of an unbound device, although other mobile phones can search for the device via Bluetooth, they must be bound by touching the device.

9. Take ECG recording using the Midong Health Watch

9.1 Before taking each recording:

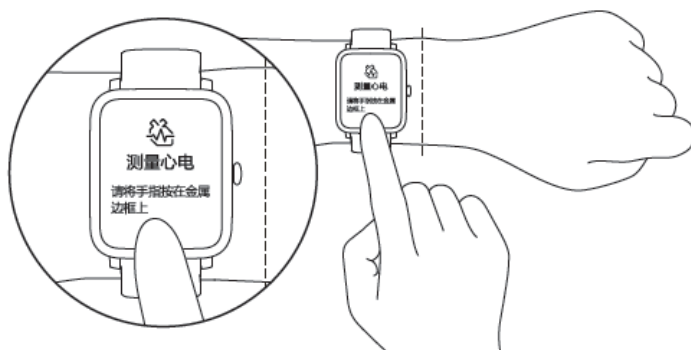
- Disconnect headphones, charging cable, or any other connected devices.
- Clean the two electrode sensors with an alcohol-based sanitizer.
- Make sure the connection of the Midong Health Watch and the *Amazfit Health app*.

9.2 Measurement

9.2.1 Wear the ECG Recorder wristband on the left wrist, avoiding the carpal bone. (If wearing on the right wrist, follow the instructions by swapping left and right)

9.2.2 Adjust the wristband to the appropriate tightness so that the electrode sensors contact the skin.

9.2.3 Rest your right forefinger on the front electrode. Press your right forefinger with enough force to ensure that the rear electrode sensors are in contact with the skin of your left wrist for the entire duration of the recording. Remain still while recording, and the Midong Health Watch, forearm, and hands should not move while recording.



The recording takes 60 seconds offline or 240 seconds online, as directed by the user.

- 30 seconds offline recording: the ECG data is temporarily stored on ECG Record memory before transmitted to the *Amazfit Health app* and Cloud servers.
- 60 seconds online recording: The ECG data is transmitted to the *Amazfit Health app* and Cloud servers in real-time.

10. Once the recording is finished

Immediately after the recording is complete, the software automatically saves the ECG data.

The ECG data displays for review. The review screen allows you to scroll through the ECG by swiping your finger across the screen, and you can pinch and zoom to scale the ECG. There are also options to edit user's information, review previous or next recordings.

You can also order an ECG analysis report to have your ECG recording reviewed by a professional.

When you have finished reviewing the ECG recording, either press the 'Home' button to exit the app or press the 'Back' key to return to the 'Record' screen, where you can then record another ECG.

11. View previously recorded ECG recordings on your mobile phone

Historical records are displayed on the page of "History". To view the recordings, open the menu bar by pressing the button on the upper left corner, and then choose "History". On the History page, historical recordings of the current month display in time sequence. To view the recordings of another year/month, click on the date above the recordings so that a time widget pops up. Scroll up or down to choose the desired date.

Measurement mode, date, start time, and duration are shown in every single record card. Click on a card; it expands into several time segments. Click on a time segment to view the electrocardiograph within the period.

12. Editing user profile

To view or edit personal profile, open the menu bar by pressing the button on the upper left corner, and then click on the portrait area. In the personal profile page, nickname, sex, date of birth, height, and weight can be modified.

13. ECG Analysis

Subsequent recordings:

- After an ECG recording is complete, the ECG is analyzed to determine if it is at least 60 seconds long, if it is no Atrial Fibrillation, Unclassified, if Atrial Fibrillation is present, or if it is too noisy to interpret.
- To view the ECG, please visit the history page.
- The presence of Atrial Fibrillation (AF) in your ECG results may present only potential findings. If you are experiencing any symptoms or have concerns, contact your physician.
- Unreadable ECG results determine that you didn't have proper ECG recording for analysis. You might try to re-record your ECG.
- ECG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- All ECGs are synced to the Amazfit Health app. You may use the phone app to send your ECGs for physician analysis.

14. Troubleshooting

| Problem | Solution |
|----------------------------|---|
| The device is not working. | Option 1: Check the battery has power. Option 2: Ensure that the <i>Amazfit Health app</i> has access to the device. Option 3: Close the device to the mobile phone as much as possible |

Anhui Huami Healthcare Co.,Ltd.

| | |
|---|---|
| | Option 4: Try to turn off and on the Bluetooth of the mobile phone or restart the mobile phone. |
| I have a lot of artifact, noise, or interference in my recording or no ECG recording. | Option 1: Ensure that your ECG Record, arms, and hands remain still during recordings. Option 2: Clean the electrode sensors on the device with an alcohol-based sanitizer. Option 3: If your skin is very dry, use a water-based lotion before recording. Option 4: When recording, relax your arms and hands to reduce muscle noise. |
| Failure in data uploading | The data uploading is related to the network environment; you can try to change the network environment (switch to WiFi/4G). |

15. Specifications

Performance characteristics

ECG Channels: Single Channel

Input Dynamic Range: 10 mV Peak-to-Peak

Memory length: Practically unlimited

Recording format: Continuous

Circuitry

Frequency Resp.: 0.67 Hz to 40 Hz

CMRR: ≥ 60 dB

Input impedance: > 10 M Ω

Differential range: ± 5 mV

A/D Sampling Rate: 250 samples/second

Resolution: 22 bit

DC offset correction: ± 300 mV

Input

Frequency: 2400 - 2483.5 MHz

Modulation: GFSK

Frequency: 2400~2483.5MHz

MAX Transmitted power: 0 dBm

Power requirement

AC Input: 100V - 250V, 50Hz/60Hz to 5VDC Adapter with 5V USB Adapter Cable

Battery Type: DC 3.85V, 190 mAh, Lithium battery

Charging Time: 2.5 hours from flat

Operating Time: 24 hours on a full charge

Physical characteristics

Midong Health Watch: 42 × 35 × 12.5 mm; 25 grams

Wristband length: 118~195 mm

Environment specifications

Operational temperature: +10°C~+40°C

Operational humidity: 30%~75% (non-condensing)

Storage temperature: -10°C~+45°C

Storage humidity: 10%~95% (non-condensing)

16. ELECTROMAGNETIC & OTHER INTERFERENCES

The Amazfit Health Watch has been tested and deemed in conformance with the relevant requirements in IEC60601-1-2:2014 Class BF for Electromagnetic Compatibility (EMC).

The Midong Health Watch has been tested with relevant requirement standard IEC60601-1-11:2015.

17. Electrical safety

17.1 Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified in Table 1. The customer or the user of the system should ensure that it is used in such an environment.

WARNING

- The use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- In addition to the accessories provided by the equipment manufacturer, the use of other accessories may cause increased electromagnetic radiation or reduce electromagnetic immunity, resulting in equipment failure.
- Stay away from active high-frequency surgical equipment in hospitals and RF shielded rooms for systems used for magnetic resonance imaging, where electromagnetic interference is high.

Table 1 Electromagnetic Emissions: Environment Guidance

| Emissions Test | Compliance | Electromagnetic Environment Guidance |
|--------------------------|------------|---|
| RF emissions CISPR 11 | Group 1 | The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | |

17.2 Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified in Table 2.

The customer or the user of the system should ensure that it is used in such an environment.

NOTE

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 2 Electromagnetic Immunity

| Immunity Test | Input/ Output Port | IEC 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---------------------------|--|----------------------------------|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | Enclosure port | ±8 kV contact ±15 kV air | ±8 kV contact ±15 kV air | The table should be wood. If the table is covered with synthetic material, the relative humidity should be at least 30%. |
| Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8 | Enclosure port | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Radiated RF IEC 61000-4-3 | Enclosure Port | 10 V/m 80 MHz to 2.7 GHz | 10 V/m 80 MHz to 2.7 GHz | For recommended separation distances, see Table 6 |
| Proximity fields from RF wireless communications equipment IEC 61000-4-3 | Enclosure port | 27 V/m 380 MHz to 390 MHz 28 V/m 430 MHz to 470 MHz, 800 MHz to 960 MHz, 1700 MHz to | Same as IEC 60601-1-2 test level | |

| | | | | |
|--|--|--|--|--|
| | | 1990 MHz, 2400 MHz to 2570 MHz | | |
| | | 9 V/m 704 MHz to 787 MHz, 5100 MHz to 5800 MHz | | |
| <p>Cables connected to the system may affect its immunity to the electromagnetic phenomena listed in Table 5. Use only cable types and lengths listed in Table 2 to minimize the change of performance degradation due to these types of electromagnetic phenomena.</p> <p>The transducers used with the system may affect its immunity to the electromagnetic phenomena listed in Table 5. Use only the transducers listed in Table 3 to minimize the chance of performance degradation due to these types of electromagnetic phenomena.</p> <p>Accessories used with the system may affect its immunity. Use only the transducers listed in Table 4 to minimize the chance of performance degradation due to these types of electromagnetic phenomena.</p> | | | | |

17.3 Recommended Separation Distance

Table 3 provides guidance on the distances any radio frequency (RF) transmitting equipment should be kept away from the system to reduce the risk of interference with the imaging system. Table 6 lists the recommended separation distances between portable and mobile RF wireless communications equipment and system.

Table 3 Recommended Separation Distances

| Immunity of RF wireless communications equipment Test level(V/m) | Maximum Power(W) | Band(Hz) | Distance(m) |
|--|------------------|-----------|-------------|
| 27 | 1.8 | 380-390 | 0.3 |
| 28 | 2 | 430-470 | 0.3 |
| 9 | 0.2 | 704-787 | 0.3 |
| 28 | 2 | 800-960 | 0.3 |
| 28 | 2 | 1700-1990 | 0.3 |
| 28 | 2 | 2400-2570 | 0.3 |








Note: Where P is the maximum power in W.E is the immunity test level in V/m, and d is the minimum separation distance in m.

WARNING

Anhui Huami Healthcare Co.,Ltd.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Wearable dynamic Midong Health Watch, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

18. Equipment symbols

| | |
|---|---|
|  | Type BF Applied Part |
|  | WEEE – Properly Dispose of Electronic Waste |
|  | Consult Instructions for Use / User Manual |
|  | Manufacturer |
|  | Temperature Limits (Operational) |
|  | Relative Humidity Limits (Operational) |
| SN | Serial Number |
|  | recyclable |

19. Manufacture and date



Anhui Huami Healthcare Co., Ltd.

12th Floor, Building A4, National Animation Industry Base, No.800 Wangjiang West Road,
Hefei City, Anhui Province, China

Tel: 400-8850-817

Email: hmhealth@huamihealth.com



Date of manufacture: See the package

Date of issuance:2020.02.19

FCC Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with 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 equipment 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 into 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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.