EPI Mobile Health EPI Mini W518i Portable ECG Recording User Manual

User Assistance Information

Company Contact Details

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Inside this box you will find

1. EPI Mini W518i X 1
2. Charger (Model No: AU1050501e) X 1
3. USB cable X 1
4. User Manual X 1

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Symbols

Symbols	Meaning
	Follow Instructions for Use
	Caution. Please refer to safety-related notes accompanying this instrument
	Temperature limitation (Store at)
	Humidity limitation (Store at)
	Type BF applied part
	Serial Number

	Indicates separate collection for electrical and electronic equipment (WEEE).
IP20	Protected against ingress of solid foreign objects greater than or equal to 12.5 mm diameter per IEC 60529. Not protected against ingress of water
CE 0120	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
CE 2280 ①	CE Marking indicating conformance to R&TTE directive 1999/5/EC
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a healthcare practitioner
EC REP	Authorized Representative in the European Community
	Manufacturer name and address

Note: This device is registered in USA as Rx only for the US market.

For your safety, please follow all operating and safety instructions in this user guide

Indications for Use

EPI Mini W518 is a portable single lead electrocardiogram (ECG) recording device. It is capable of recording, storing and sending several leads using different configurations allowing mobile recording, storing and sending of ECGs on-the-go. This provides the user with instant access to information about their heart, within the limitations of a traditional 12 lead ECG. It serves the purpose of a mobile and highly portable ECG recording device. The device is used for ad-hoc recording of ECGs when cardiac symptoms are present to allow the detection of abnormal heart activity. The target patient population includes but it is not limited to users who are at risk of heart disease, have existing heart conditions and/or users who show symptoms suggestive of heart disease. The device is not meant to entirely replace the clinical 12 lead ECG machine.

ECG data is recorded for 30 seconds each time by the user. Recorded ECG data is stored on the EPI Mini and can be sent to a Smartphone via Bluetooth. ECG data sent from the EPI Mini is received and stored for viewing on the Smartphone using the EPI Mini mobile software application (mobile app). Users are able to view their ECGs using the mobile app, as well as resend or delete any of these data via the app to allow the doctor to monitor their conditions. The ECG data recorded by the device are not designed or intended for medical diagnosis. Conditions such as arrhythmia can only be diagnosed by a doctor through a special examination.

Warnings and Cautions

Contraindications

Users who have pacemakers or other stimulators implanted should not use this device to record any modified pre-cordial leads and should strictly be limited to using the modified limb leads for ECG recording (device should be kept at a minimal distance of 9 inches away from the implanted pacemaker or other stimulators)

For your safety, please take note of the following warnings.

Warnings

- ✓ Do not use this device in places with flammable substances like anaesthetic gas or pressurized oxygen.
- ✓ Do not self-diagnose ECG. Always consult your doctor. Self-diagnosis or self-treatment may lead to deterioration in your condition.
- ✓ Do not use this device around electromagnetic scanning like MRI scans.
- ✓ Do not use this device on people with sensitive skin or allergies.
- ✓ Do not attempt to use the device over or through clothing.
- ✓ Use only the original charger and the original USB data cable for charging. Use of other chargers and USB cables may cause unwanted electrical risk.
- ✓ Do not measure ECG when this device is charging.
- ✓ Do not plug the USB cable to this device during recording of ECG.
- ✓ Keep out of reach of infants and small children.

For your safety, please take note of the following cautions.

Cautions

- ✓ Do not use this device for any purpose other than obtaining an ECG.
- ✓ Do not record ECG where this device will be exposed to strong electromagnetic forces.
- ✓ Do not expose the unit to strong shocks or vibrations. Do not drop or step on the unit.
- ✓ Do not use for any purpose other than obtaining an electrocardiograph.
- ✓ Do not take measurements in a moving vehicle.
- ✓ If electrodes are dirty, please wipe with dry soft cloth before recording ECG.
- ✓ Only use this device in accordance with instructions provided from the manufacturer.
- ✓ The device will automatically shut down after 2 minutes of non-use.
- ✓ Do not induce excessive shock, vibration, external force onto this device.
- ✓ Do not disassemble, repair, or modify the unit.
- ✓ Charger input voltage is 100V – 220V. Do not disassemble the charger.
- ✓ Do not short-circuit the charger.

- ✓ The device and charger are not waterproof. Avoid direct exposure to water or dirt and prolonged exposure to sunlight.
- ✓ Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.
- ✓ Do not sterilize this device in an autoclave, ultraviolet sterilizer or gas sterilizer.
- ✓ When storing the device, avoid exposure to direct sunlight or heat.
- ✓ The device should be stored under the storage temperature range where the temperature is between 0°C and 40°C and the humidity is between 35% and 85%.
- ✓ The device should be stored in the room without acid, alkali and harmful gas.
- ✓ Avoid exposure to violent vibration, rain, sunshine and high humidity during transportation.
- ✓ Avoid extremes in temperature and humidity. This device and charger are designed to be used in environments where the temperature is between 5°C and 38°C and the humidity is between 35% and 85%.
- ✓ Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- ✓ In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device.

Description of Device

There are 4 function keys.

1) **"Power"** button / **"Back"** button.

2) **"Enter"** button.

3) **"Up"** button.

4) **"Down"** button.

Note that the device will automatically shut down after 2 minutes of non-use to prolong battery life.

Environmental conditions that affect use

- ✓ EPI Mini is designed to be used in environments where the temperature is between 5°C and 38°C and the humidity is between 35% and 85%.
- ✓ To avoid interference with other electronic devices, please avoid placing other electronic equipment sensitive to radio frequency (RF) and magnetic fields too close to the EPI Mini. Consult the manufacturers of your electronic devices to solve any interference problems you experience.
- ✓ Standby time data provided by manufacturer is based on the ideal working environment. Actual time may vary and depends on the environment, and usage method.

Classification of degree of protection/Type BF

The EPI Mini's sensors are conductive in nature and classified as type BF applied parts. Should a leakage current occur, there is sufficient protection to prevent users from a serious electric shock.

Getting Started

Charging the device

Please charge EPI Mini before use. To charge EPI Mini, insert the original USB cable into the device and connect the other end to the USB port of the original charger. The screen will show a charging screen with all the normal functions disabled. Do not use the device during charging. The screen will show **"fully charged"** (Battery icon with 'F' in red font) when battery is fully charged.

Note: The rechargeable battery has a limited number of charge cycles and might eventually need to be replaced. Battery life varies based on use.

Pairing the device with your phone

1. Power on the EPI Mini by holding the "Power" button for 3 seconds
2. **Go to Settings** >> **System Info** >> **BT Address**, record the characters on the screen.
3. In your phone, go to **Menu** >> **Settings** >> **Bluetooth**. Select to scan for new devices. Select **"EPI Mini"** or corresponding BT Address to pair the device.

Download Application

Please download the application EPI mHealth from your Smartphone's respective application ("app") stores (i.e. Google Play Store, BlackBerry App World, Apple App Store).

You may also visit our website at www.epi.com.sg and refer to the Support section to download the application and other guides on how to setup the respective Smartphone.

Operating Instructions

Recording your ECG

1) Select the **"Record ECG"** tab in your EPI Mini. Press the **"Enter"** button and read the instructions on the screen. Hold the device as shown in the image below. Ensure that there is good surface contact with the electrodes leads and press the **"Enter"** button again to start recording.

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2) After recording, ensure that the arrow is on **"Yes"** then press the **"Enter"** button to send the ECG. You should see **"Data Sent"** appearing on the EPI Mini, and **"Data Received"**, **"Connecting to Server"**, **"Data sent successfully"** appearing sequentially on the application of your Smartphone.

3) You should obtain a reply on your Smartphone within 10 minutes.

ECG Manager

In this function, you can send or delete previous ECGs.

Press the "**Up**" or "**Down**" button to the corresponding option and "**Enter**" button to select option.

To return to the previous menu, press the **"Back"** button.

Date/Time

To change the Date,

Go to Settings >>> **Date/Time** >>> **Set Date**

Press the "**Up**" or "**Down**" button to change the value.

Press the **"Enter"** button to move to the next value.

After the last value, press the "**Enter**" button to save changes.

To return to the previous menu, press the **"Back"** button.

To change the Time,

Go to Settings >>> **Date/Time** >>>
Set Time

Press the "**Up**" or "**Down**" button to change the value.

Press the **"Enter"** button to move to the next value.

After the last value, press the "**Enter**" button to save changes.

Language

To change language,

Go to Settings >>> **Language.**

Press "**Enter**" button.

Press the "**Up**" or "**Down**" button to scroll.

Press "**Enter**" button to confirm the desired language.

To return to the previous menu, press the **"Back"** button.

User Settings

To edit User Profile,

Go to Settings >>> **User Settings** >>> **Edit User Profile**

Select profile to edit, use the "**Up**" or "**Down**" button to change the value, press **"Enter"** button to save changes.

To change User,

Go to Settings >>> **User Settings** >>> **Select User Profile**

Use the "**Up**" or "**Down**" button to select the desired user, press **"Enter"** button to confirm.

To return to the previous menu, press the **"Back"** button.

System Information

Go to Settings >>> **System Info.**

You can check your Firmware version by going to FW Version.

You can view the device name **"EPI Mini"** in Device Name.

You can view your Bluetooth address by going to **"BT Address"**.

To return to the previous menu, press the **"Back"** button.

Cleaning and Maintenance

✓ Clean your device with a soft and dry cloth.

✓ Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.

✓ Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.

✓ Do not repair, disassemble and modify this device.

✓ This device does not require calibration during its expected life cycle.

Storage and Transport

✓ When storing the device, avoid exposure to direct sunlight or heat.

✓ The device should be stored under the storage temperature range. If the device will be stored for a long time, the recommended conditions are:

Temperature: 0°C to 40°C
Relative humidity: 35% to 85%

✓ The device should be stored in the room without acid, alkali and harmful gas.

✓ Avoid exposure to violent vibration, rain, sunshine and high humidity during transportation.

Troubleshooting Guide

Problem	Possible Cause	Recommended Solution
EPI Mini cannot be switched on	The battery is out of power.	Charge the battery.
EPI Mini cannot be charged	The charger is damaged.	Change charger.
Noisy ECG Signal	Fingers are dry.	Moisten hands with a damp towel.
	Integrated electrodes are dirty.	Refer to Cleaning and Maintenance.
	Excessive movement during measurement.	Check instructions and repeat measurement.
Error message "Failed to send Check BT connection with phone"	EPI Mini not connected to Smartphone.	Follow the instructions on "Pairing the device with your phone".
Unable to send ECG to server	Smartphone not connected to Internet.	Check internet connection on your Smartphone.

Specifications

Product Name: EPI Mini
Model: W518i
Dimension: 75.4(L) mm x 46.4(W) mm x 15.0(H) mm
Weight: 58 g
Display: 2" 220X176 TFT-LCD
Power rating: 3.7V 80mA
Battery Life:
     Operating mode: over 6 hours
     Standby mode: over 5 days

Wireless Communication: Bluetooth 4.0 Low Energy

Operating Environment: 5°C to 38°C (41ºF to 100ºF)/
     35% to 85% RH

Storage Environment: 0°C to 40°C (32ºF to 104ºF) /
     35% to 85% RH

Classifications per IEC 60601-1:

Degree of protection: Type BF-Applied Part

Enclosure Degree of Ingress Protection: IP20

Note: Specifications are subject to change without prior notice

This product meets EMC standards IEC60601-1-2:2007. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Using this device with or near other medical/electrical equipment could produce mutual interference. Be sure to read the Instruction Manual for correct installation and use. Also, be sure to read the Instruction Manuals for all other electronic equipment nearby.

Federal Communications Commission (FCC) Notice

This device 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 device generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the device 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 distance between the device and the receiver.
• Connect the device to an outlet on a circuit different from the outlet where the receiver is connected
• Consult the dealer or an experienced radio/TV technician for assistance.

The device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This device has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.

CAUTION:
Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

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