

EPI Mobile Health EPI Mini W518 Portable ECG Recording User Manual

User Assistance Information

Company Contact Details

EPI Mobile Health Solutions (S) Pte Ltd
8 Ubi View, Serial System Building, #03-01
Singapore 408554
Tel: (+65) 6262 6868
Fax: (+65) 6363 3030
Email: info.enquiries@epi.com.sg
www.epi.com.sg







Inside this box you will find






1. EPI Mini W518 X 1
2. Charger (Model No: AU1050501e) X 1
3. USB cable X 1
4. User Manual X 1

Table of Contents

Symbols	3
Indications for Use	5
Warnings and Cautions	6
Description of Device	8
Environmental conditions that affect use.....	9
Classification of degree of protection/Type BF	9
Getting Started	9
Charging the device	9
Pairing the device with your phone	9
Download Application.....	9
Set-up and Connection (For Android)	10
Operating Instructions	12
Recording your ECG	12
ECG Manager	13
Date/Time	13
Language	14
User Settings	14
System Information	15
Cleaning and Maintenance	15
Storage and Transport	15
Troubleshooting Guide	16
Specifications	17

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

	<p>Indicates separate collection for electrical and electronic equipment (WEEE).</p>
	<p>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</p>
	<p>CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.</p>
	<p>Authorized Representative in the European Community</p>
	<p>Manufacturer name and address</p>



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.

Warnings and Cautions

Contraindications

Users who have pacemakers 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)

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 cable may expose to unwanted electrical risk.
- ✓ Do not measure ECG when this device is charging
- ✓ Do not operate the device during charging.
- ✓ 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 take 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 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%.
- ✓ 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 your EPI Mini before use. To charge your 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 operate the device during charging. The screen will show **“fully charged”** (Battery icon with 'F' in red font) when battery is fully charged.

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

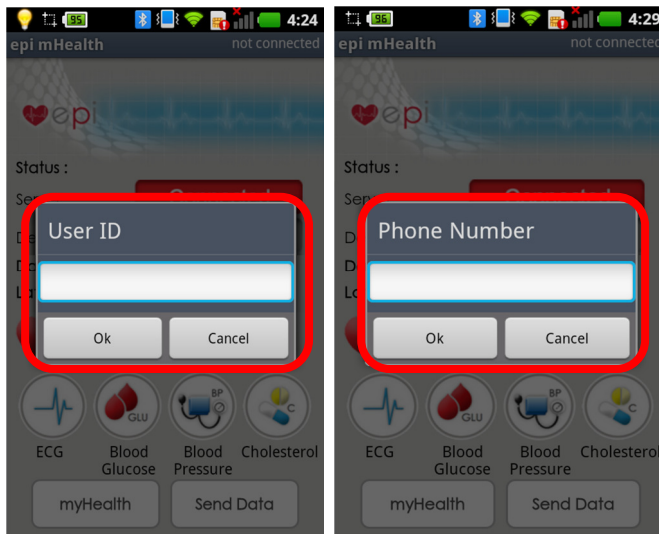
Please download the application EPI mHealth from your Smartphone's respective application (“app”) stores (i.e. Google Play Store, BlackBerry App World, Apple App Store).

You may also download the application from our website <http://epimhealth.com.sg/downloads>

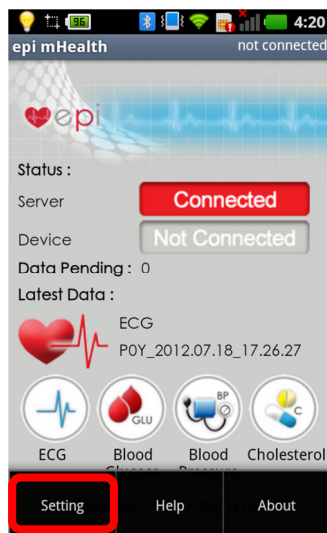
You may refer to the App User guide on how to setup the respective Smartphone from our website <http://epimhealth.com.sg/technicalsupport/>

Set-up and Connection (For Android)

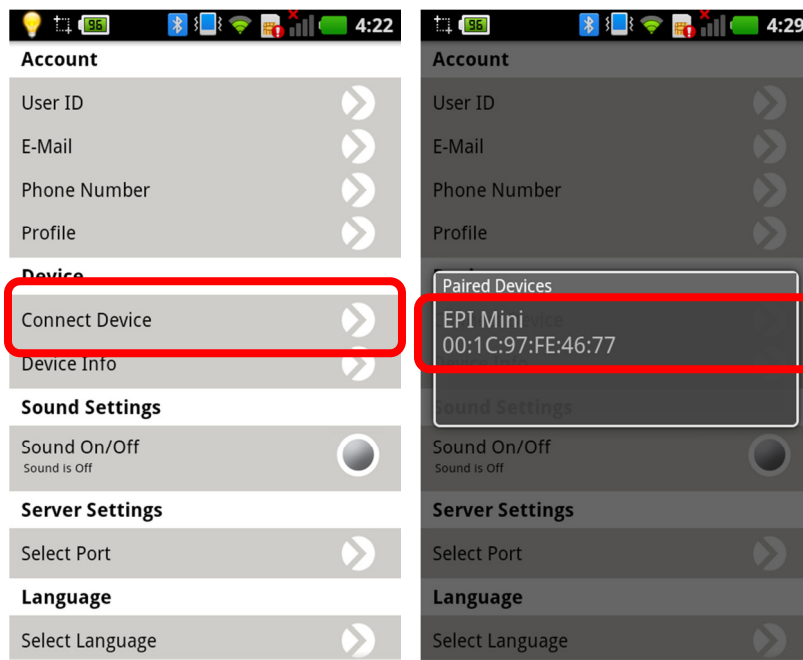
1. On first time use of the app, you will be prompted to enter your User ID and mobile number. These can be found in the email sent to you when you activate your device.



2. From the App main screen, access Settings from the Menu



3. Select Connect Device and select the EPI Mini displayed on the list (ensure that the EPI Mini is powered on before connecting)



4. You will be prompted upon successful connection: **“Connected to EPI Mini”** and a red connected icon next to the EPI Mini on the Main Screen of the app. There will also be a Bluetooth icon on the top right of the screen on the EPI Mini



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.



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”**, **“Succeed to send data to server”** appearing sequentially on the application of your Smartphone.

3) You should obtain a reply to your Smartphone in about 5 to 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 go back 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 values.

Press the “**Enter**” button all the way to the end to save changes.

To go back 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 values.

Press the “**Enter**” button all the way to the end to save changes.



Language

To change language,

Go to Settings >>> Language

Select desired language.

To go back 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 values, press “**Enter**” button to select.

To change User,

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

Use the up or down button to the desired user, press “**Enter**” button to select.

To go back 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 see the device name “**EPI Mini**” in Device Name.

You can see your Bluetooth address by going to “**BT Address**”.

To go back 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 recommend condition is:
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.
Error message “ failed to send Check BT connection with phone”	EPI Mini not connected to Smartphone	Follow the instructions on Page 9 “Pairing the device with your phone”.
Unable to send ECG to server	Smartphone not connected to Internet	Check internet connection on your Smartphone.

**For enquiries,
please call our hotline at
+65-6262 6868**

Specifications

Product Name:	EPI Mini
Model:	W518
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:	
<i>Operating mode:</i>	over 6 hours
<i>Standby mode:</i>	over 5 days
Wireless Communication:	Bluetooth Ver 2.1 + EDR Class II
Operating Environment:	5°C to 38°C (41°F to 100°F) / 35% to 85% RH
Storage Environment:	0°C to 40°C (32°F to 104°F) / 35% to 85% RH
Classifications per IEC 60601-1:	
<i>Degree of protection:</i>	Type BF-Applied Part 
<i>Enclosure Degree of Ingress Protection:</i>	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.