REVLIS

Instructions for Use (IFU)
for
Revlis ECG Monitor
(CMP-121A)

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Introduction

The Revlis ECG Monitor (the “Device”) is a personal electrocardiogram (ECG) monitoring device intended to acquire and record a single-lead ECG (Lead I), providing a single-channel view of the heart’s electrical activity. The ECG data are transmitted via Bluetooth wireless technology to the Fiona Application (“Fiona App”) installed on a compatible smartphone.

1. The top surface of the Device contains two electrodes intended for contact by the user’s left and right fingers during ECG measurement.
2. The Device is powered by a coin cell battery.
3. The Device is intended for use with a compatible smartphone and the Fiona App. The Fiona App is designed for offline operation and does not require an internet connection during use. ECG data are stored locally on the smartphone and are not transmitted to external cloud servers.
4. The Device firmware is validated prior to release, and firmware updates are not required for normal operation.
5. The Device does not provide automated diagnostic interpretation and is not intended to replace conventional diagnostic methods, clinical evaluation, or physician judgment.
6. ECG recordings should be reviewed and interpreted only by qualified healthcare professionals.
7. The Device includes protective control features intended to reduce the risk of unintended setting modifications.

Product Contents

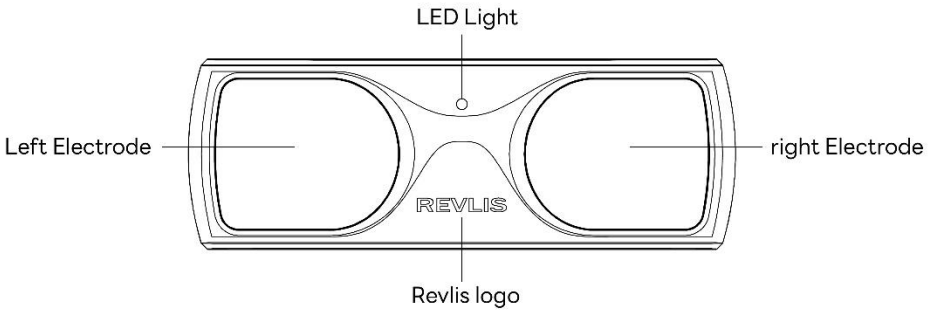
The product package includes:

- One product package box
- One Instructions for Use (IFU) manual
- One Revlis ECG Monitor (the “Device”)

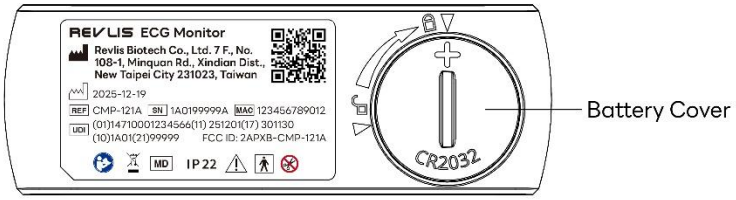
Note:
The Device requires one CR2032 coin cell battery for operation, the battery is not included in the package.

Device Overview

Front View

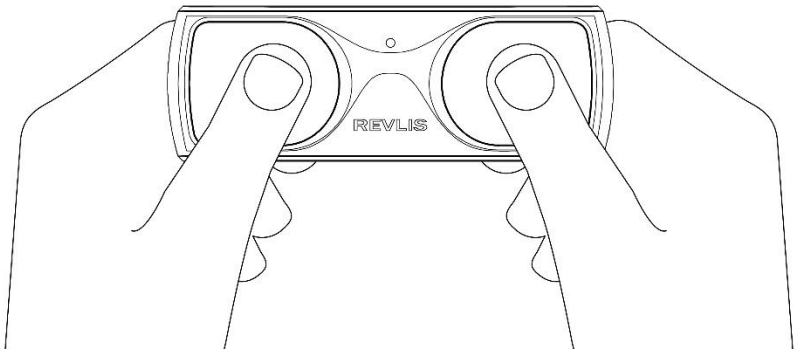


Back View



Holding Orientation

Hold the device in the correct orientation.



Intended Use

The Revlis ECG Monitor is intended to acquire, display, store, and transmit single-lead ECG (Lead I) signals and heart rate information for adult users in home environments.

Indications For Use

The Device is intended for use by lay users aged 22 years and older in home environments to record, display, store, and transmit single-lead ECG (Lead I) data. ECG recordings should not be used as the sole basis for diagnosis or treatment decisions, and should be reviewed by qualified healthcare professionals.

Contraindications

This Device is not intended for use in patients with implanted cardiac pacemakers or other implantable electronic devices. The Device is also not intended for use in pediatric patients.

Expected Service Life

The expected service life of the Device is 2 years when used, stored, and maintained in accordance with this Instructions for Use under normal operating conditions.

Safe Disposal of the Device

Do not dispose of the Device in household waste. Dispose of the Device in accordance with applicable local, state, and national regulations for electronic waste and battery disposal. Improper disposal may result in environmental contamination.

Do not cut, crush, incinerate, shred, or otherwise physically damage or dismantle the Device.

Operation Instruction

1. Installing the battery

（1） Open the product packaging and remove the Device.

（2） Use a coin (or a similar tool) to rotate the battery cover on the back of the Device and open it.

（3） Insert one CR2032 coin cell battery with the positive (+) terminal facing outward. Ensure the coin properly fits into the groove of the battery cover.

（4） Rotate the battery cover to close and secure it.

（5） After the battery is installed, the Device will enter standby mode, and the LED indicator will remain off.

（6） When the battery is low, the LED indicator will flash in a different pattern (on for 0.5 seconds and off for 5 seconds). It is recommended to replace the CR2032 coin cell battery as soon as possible.

2. First-time installation of the Fiona APP

（1） Download the Fiona APP from the designated app store (App Store or Google Play).

（2） Ensure that Bluetooth is enabled in your smartphone settings.

（3） This App is compatible with supported iOS and Android operating system versions.

3. Single-lead ECG (Lead I) Measurement

（1） Please sit comfortably in a stable position and rest quietly for at least 3 minutes before measurement. If you have recently exercised or are feeling emotionally stressed or excited, rest for at least 30 minutes and wait until your heart rate has stabilized before taking the measurement.

（2） Open the Fiona APP and tap “Measurement.”

（3） Place both thumbs steadily on the electrode surfaces on both sides. Once the device is activated, the LED indicator will light yellow-green for approximately 0.5 seconds and then turn off for about 2 seconds, indicating successful startup.

（4） After the device is powered on, the APP will automatically connect via Bluetooth. Once the Bluetooth connection is successful, tap “Start.”

（5） After activation, keep both thumbs in contact with the electrodes on both sides while maintaining a stable seated posture. Avoid applying excessive pressure and ensure the device is held in the correct orientation. During measurement, the LED indicator will continue flashing in a pattern of 0.5 seconds on and 2 seconds off, indicating that recording is in progress. Do not remove your fingers before the measurement is completed. Once the LED indicator turns off, you may remove both thumbs and wait for the application results.

（6） Finally, the APP will display the recorded ECG waveform and calculated average heart rate.

4. Device Operating Modes and LED Indicators

Operating Mode	LED Indicator	Description
Standby Mode	Off	The Device is powered on but not in use.
Working Mode (Activation)	On for 0.5 seconds → Off for 2 seconds	The Device has been activated.
Measurement in Progress	Continuous flashing	ECG is being recorded.
Measurement Completed	Off	Measurement has been successfully completed.
Low Battery Warning	On for 0.5 seconds → Off for 5 seconds	Battery level is low.
Measurement Interruption	LED remains on continuously	Measurement is interrupted due to loss of finger contact with electrodes.

Warnings and Precautions

1. Device limitations: The Device records single-lead ECG (Lead I) signals only. It does not analyze or interpret ECG data, detect cardiac conditions, or provide a diagnosis.
2. Heart rate values are estimates derived from the recorded ECG signal and may be affected by motion artifacts, poor electrode contact, or signal noise.
3. The Device is not intended for emergency or continuous cardiac monitoring.
4. The Device does not provide continuous real-time cardiac monitoring.
5. Do not use the Device output as the sole basis for medical diagnosis, treatment decisions, medication use, or clinical decision-making. All recordings must be reviewed by a qualified healthcare professional.
6. The Device may not detect all arrhythmias or cardiac conditions, including low-amplitude signals or recordings affected by noise, motion artifacts, or poor contact.
7. Seek medical attention immediately if you experience chest pain, shortness of breath, fainting or near-fainting, palpitations, or other concerning symptoms, regardless of Device readings.
8. The Device is MR Unsafe and must not be used in MRI environments or in strong electromagnetic fields (e.g., RF equipment).
9. Signal quality limitations: Improper electrode contact, excessive pressure, poor posture, movement, sweating, or excessively dry/moist skin may result in degraded signal quality or inaccurate recordings.
10. Performance may be affected when used near wireless communication equipment.
11. Ensure both thumbs maintain continuous contact with the electrodes during measurement. Premature release may interrupt recording.
12. Do not use the Device outside the environmental conditions specified in this manual.
13. Do not use in wet environments, during thunderstorms, or where electrical hazards may exist. Do not immerse the Device in liquids.
14. Replace the battery promptly when the low-battery indicator appears.
15. Coin cell batteries pose a choking hazard. During battery replacement, keep the Device and batteries out of reach of infants and young children. If ingestion or insertion is suspected, seek immediate medical attention, as it may cause serious injury.
16. Do not replace the battery while the Device is in use or in contact with the user.
17. Keep the Device out of reach of children, pets, and pests to prevent damage or

accidental ingestion.

18. Do not disassemble, modify, or repair the Device. Service should be performed only by the manufacturer or authorized distributor.
19. Read and follow the Instructions for Use carefully. If in doubt, contact the manufacturer or authorized distributor.

FCC compliance

This device complies with Part 15 of the FCC Rules.

FCC ID: **2APXB-CMP-121A**

Federal Communications Commission (FCC) Interference Statement

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.

Any changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment.

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.

RF exposure statements

This product is based on SAR assessment and the user manual must have the following warnings “This device meets the government’s requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels. The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid.”

Maintenance and Cleaning

Store the Device in a clean, dry environment within the specified storage and environmental conditions described in this manual.

1. Service and repair

（1） No service or repair should be performed on the Device other than the maintenance procedures described in this section.

（2） The Device contains no user-serviceable internal components.

（3） The Device does not require calibration during its service life, and contains no operator-adjustable calibration controls.

2. Cleaning

（1） The Device is intended for single-patient use and for contact with intact skin only. Routine cleaning is sufficient.

（2） Clean the electrodes using clean water and wipe with a clean, lint-free soft cloth as needed.

（3） Do not use abrasive cleaners or abrasive materials.

（4） Do not immerse the Device in liquid or expose it to excessive moisture or fluids.

3. Exterior visual inspection

（1） Inspect the electrodes for deformation, surface damage, or corrosion.

（2） Inspect the device housing and external surfaces for cracks, deformation, or other visible damage. If any damage is observed, discontinue use and contact the manufacturer or authorized service provider.

4. Battery replacement

（1） Battery type: CR2032 coin cell battery compliant with IEC 60086-4.

（2） Insert the battery with correct orientation, ensuring the positive (+) terminal faces upward.

（3） The battery cover requires a tool (e.g., a coin) for opening. A tool (e.g., a screwdriver) is required for battery removal to reduce the risk of accidental swallowing.

（4） Remove the battery if the Device will not be used for an extended period.

Troubleshooting

If you experience difficulties using your Revlis ECG Monitor, refer to the troubleshooting guide below.

If the problem persists after troubleshooting, discontinue use and contact customer support.

1. **My Revlis ECG Monitor is not working**
   - A. Verify Battery state
     - i. Use the correct CR2032 coin cell battery.
     - ii. Ensure the battery polarity matches the markings on the product when inserting the battery.
     - iii. When the battery power is low, the LED indicator will flash in a different pattern (on for 0.5 seconds and off for 5 seconds, with a longer off interval compared to normal operation). Replace the CR2032 coin cell battery as soon as possible.
   - B. Verify Device Activation

     When holding the device and touching both electrodes with your thumbs, the central LED indicator will illuminate yellow-green, indicating that the device has entered operating mode.

   - C. Verify Smartphone Bluetooth Settings
     - i. Ensure that Bluetooth is enabled on your smartphone.
     - ii. For Android smartphones, ensure that Location Services are also enabled to allow Bluetooth device detection and connection.
   - D. Verify App Connection
     - i. Ensure the Fiona App is installed and running on the smartphone.
     - ii. Keep the smartphone within the recommended Bluetooth communication range during measurement.
2. **I am having trouble getting a clear recording**
   - A. Electrode and Skin Preparation
     - i. Clean the electrodes using a soft, damp cloth before use.
     - ii. Wash your hands with soap and water prior to recording.
     - iii. Slightly moisten the skin areas where your fingers contact the electrodes to improve signal quality.
   - B. Reduce Muscle Noise During Recording
     - i. Relax your arms and hands during recording to minimize muscle noise and motion artifacts.
     - ii. Rest your forearms and hands on a flat and stable surface while recording.
     - iii. Do not apply excessive pressure to the electrodes.
   - C. Reduce Electrical Interference
     - i. Avoid using the device near sources of electrical interference, such as electronic devices, computers, chargers, wireless routers, or other electronic

equipment.

ii. Hearing aids may introduce electrical interference during ECG recording. If applicable, turn off hearing aids before recording.

3. Additional Troubleshooting Information

A. Measurement Interrupted

i. Bluetooth communication may be unstable. Move to an environment with less wireless interference and try again.

ii. Battery power may be low. Verify the battery status of the device.

B. No ECG Waveform Displayed During Measurement

If no ECG waveform appears during measurement, the app may be connected to another nearby device. Ensure that no other compatible devices are simultaneously powered on nearby.

C. Device Damage

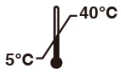
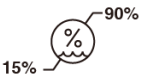
If the device appears damaged or is not functioning properly, discontinue use and contact customer service or your authorized distributor.

Technical Specification

Item		Specification
Function		Single-lead ECG (Lead I)
Dimension		W86mm*H8.6mm*D30mm
CPU		128 MHz Arm®Cortex®-M-33 processor
Memory		4Mb Flash memory
Interface		Bluetooth (BLE)
Sample rate		1,000Hz
Resolution		12 bit
Z_in		>10MΩ
CMRR		>60dB
FR		0.5Hz to 40Hz
Input dynamic range		±5mV offset ±300mV
NR		50Hz / 60Hz
Power	Sleep mode	3V/7uW
	Operating mode	3V/7mW
Operating Temp.		5°C~ 40°C
Storage Temp.		-25°C~ 70°C
Transport Temp.		-25°C~ 70°C
Operating humidity		15%~90%
Storage humidity		15%~90%
Transport humidity		15%~90%
Weight		21g (w/o batteries and peripherals)
Measurement time		30 seconds
Power supply		CR2032*1

Symbols

The packaging and labeling of the Device may include the following symbols:

Symbol	Interpretation	Symbol	Interpretation
	Manufacturer		Temperature limit
	Date of manufacture		Humidity limitation
	Catalogue number		Consult instructions for use
	Serial number		Caution
	Unique device identifier(UDI)		Type BF Applied Part
	Medical device		Do not cut, shred or attempt to destroy device
	Do not dispose with household waste		Refer to instruction manual/booklet
IP 22	IP 22		WARNING Projectile Hazard