



Device Name: Wireless ECG recording box

Model: ZHYH002

APP Name: Monerr

User Manual

Ver: 1.00.00

Intel love (Tianjin) Medical Device Co., Ltd.

NOTICE:

It is required that you read this instruction manual before trying to operate the Wireless ECG recording box and MONERR APP.

It is not recommended that you start using the device before reading the whole manual.

Failure to follow this instruction manual may result in measurement abnormalities and equipment damage. Intel love(Tianjin) Medical Device Co., Ltd. (the “Company”) assumes no responsibility for personal injury or device damage sustained by or through the use of this product.

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1. Legal

1.1 Copyright & Disclaimer

Intel love (Tianjin) Medical Device Co., Ltd. reserves the right to make changes to the information contained in this publication without prior notice. The reader should in all cases consult Intel love (Tianjin) Medical Device Co., Ltd. to determine whether any such changes have been made.

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The MONERR app is compatible with both iOS and Android phones.

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2. Warnings and Cautions

2.1 Precautions

- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.
- The equipment must be used per the requirements of this manual. Failure to properly use the equipment may result in degraded performance or loss of functionality.
- Use of the equipment near mobile and portable RF communications equipment or other electronic devices may affect the equipment.
- Other devices may emit harmful radiation or interference that could affect equipment performance.
- Use of accessories and cables other than those provided with the equipment could result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2015+A1:2020.
- The received signal maybe interfered/disrupted by other equipment operating in this frequency band (i.e.Bluetooth, other non-associated access points, microwave ovens, ISM devices, etc.) even if the other equipment complies with its applicable regulations such as CISPR 11.

2.2 Warnings

- Changes or modifications to this unit not expressly approved by the party responsible for compliance will void the user's authority to operate the equipment and any applicable manufacturer's warranty.
- The wireless ECG recording box is not a diagnostic device. This single lead ECG device should not be used for diagnostic purposes in comparison to the standard Single Lead ECG recorder obtained with typical electrode placement.
- This device cannot predict or diagnose a heart attack and should not be used for chest pain monitoring.
- The wireless ECG recording box is not a defibrillation-proof device.

- To prevent fire or shock hazard, do not expose the unit to rain or moisture.
- Refer servicing to qualified personnel only.

2.3 Contraindications

This device should not be used with active pacemakers or implanted defibrillators.

2.4 Intended User

Should be able to hold the device steady in both hands for at least 20 seconds.

Should be able to read and understand the content in the user manual.

Should understand principle of operation described in this manual.

Should be able to operate a phone.

3. Technical Specifications & Declarations

3.1 Symbols Explantion

Symbol	Description	Symbol	Description
	Type CF applied part		Caution
	Waste Electrical and Electronic Equipment (WEEE). It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.	IP22	Protected against access to hazardous parts with a finger and against vertically falling water drops when enclosure tilted up to 15°
	Date of Manufacture		Serial Number
	Manufacturer		Follow instruction for use

Symbol	Description	Symbol	Description
	Non-ionizing radiation	/	/

3.2 Technical

Characteristic	Value
Input Impedance	>10MΩ
Input dynamic range	<10% or +/- 0.05mV
CMRR	>60dB
DC offset correction	+/- 300mV
Bandwidth	0.67 Hz to 40 Hz
Recording durations	20s, 30s or 60s
Gain	5mm/mV and 10mm/mV
Transmission mode	Bluetooth Low Energy
Product Classification	Internally powered equipment Type CF applied part IP22
Battery type	3.7V 570mAh Lithium battery
Battery life	approximately 300 times
Unit Life	5 years
Software Version	1140
Operating Environment	Temperature: +5 to +40°C (41 to 104 °F) Relative Humidity: 15%~93%RH Pressure: 70.0kPa~106.0kPa
Transport & storage Environment	Temperature:-20 to +55°C (-4 to 131 °F) Relative Humidity: 10%~95%RH Pressure: 70.0 kPa~106.0 kPa
Dimensions	15cmx5cmx3.65cm
Net weight	116 (grams)

3.3 Electromagnetic Compatibility

The device meets the requirements of IEC 60601-1-2. All the accessories also meet the requirements of IEC 60601-1-2 when in use with this device.



Warnings

Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.

The device or its components should not be used adjacent to or stacked with other equipment.

The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Other devices may interfere with this device even though they meet the requirements of CISPR.

When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

Portable and mobile communication equipment may affect the performance of this device.

Other device that have RF transmitters or sources may affect this device.

This device is Magnetic Resonance (MR) unsafe.

Guidance and Manufacture's Declaration – Electromagnetic Emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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	
Harmonic emissions IEC 61000-3-2	Not applicable	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/Flicker emission IEC 61000-3-3	Not applicable	

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100kHz repetition frequency	±2 kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (100% dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°;	0% UT (100% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [equipment or system] requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
	0% UT (100% dip in UT) for 1 cycles at 0°;	0% UT (100% dip in UT) for 1 cycles	
	70% UT (30% dip in UT) for 25/30 cycles at 0°;	70% UT (30% dip in UT) for 25/30 cycles at 0°	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	0% UT (100% dip in UT) For 250/300 cycles;	0% UT (100% dip in UT) for 250/300 cycles	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	30 A/m	30 A/m	

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test	Compliance	Electromagnetic environment - guidance

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
	Level	Level	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency or the transmitter. Recommended separation distance $d = 1.2 \sqrt{p}$ $d = 0.35 \sqrt{p} \text{ 80 MHz to 800 MHz}$ $d = 0.7 \sqrt{p} \text{ 800 MHz to 2.7 GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10V/m	

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
Rated Maximum output of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.16 \sqrt{p}$	80 MHz to 800 MHz $d = 0.35 \sqrt{p}$	800 MHz to 2.7 GHz $d = 0.7 \sqrt{p}$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.12	2.24
100	12	3.5	7.0

Guidance and Manufacture's Declaration – Electromagnetic Immunity

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3.4 Declaration of Conformance

Conformance to Standards-non-clinical testing demonstrated conformance to voluntary safety IEC 60601-1 and to IEC 60601-1-2.

3.5 RF Conformance

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.

Changes or modification 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.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

3.6 Quality of Service and Security

Use of this device assures timely, reliable, accurate, and secure data and wireless data transfer when used in accordance with this manual.

- When you want to establish a wireless connection with the ECG recording box, you must input the correct communication instructions so that unauthorized access to the ECG data is prevented.
- The MONERR includes ECG data storage function.
- The MONERR connects to a phone using Bluetooth 5.0 LE secure connection.
- Intel love (Tianjin) Medical Device Co., Ltd. recommends securing the phone to avoid unauthorized access to personal data by:
 - Set automatic keypad locks to prevent unauthorized use.
 - Set a personal device PIN or password to unlock the keypad.
 - Only download apps from trusted sources.
- MONERR App is only distributed through the Google Play Store and Apple Store. If a user downloads software updates from other unauthorized channels, it will increase the risks associated with cybersecurity breaches. Intel love (Tianjin) Medical Device Co., Ltd. will not take responsibility for the consequences this may cause.

4. Overview

4.1 Indications for Use

The wireless ECG recording box is an over-the-counter device to be used by patients of adult. It is intended to record, store and transfer single channel Heart Rhythm signals and display Heart Rhythm waveforms. This 1-lead ECG recording box allows to display the ECG data to medical professionals via the Mobile software (Monerr APP).

The wireless ECG recording box combined with Monerr APP is indicated for users who are concerned about their heart rhythms and may have experienced symptoms that may suggest irregular or abnormal heart rhythms. Symptoms may include:

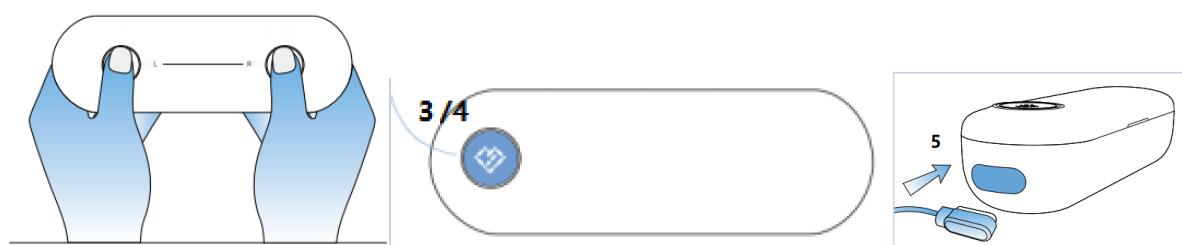
- Skipped beats
- Palpitations

- Racing heart
- Fainting and lightheadedness
- Irregular rate
- History of any related heart abnormalities

The wireless ECG recording box along with Monerr APP is not intended to substitute a hospital diagnostic ECG device. Users with an implanted pacemaker or are not recommended to use this device while the implanted device is operational. Users where their pacemaker is operational will not be able to record their ECG under normal sinus rhythm with the pacemaker on.

4.2 Description of the Device

This product consists of ECG recording box and mobile software (software name: Monerr APP). The ECG recording box is composed of a shell, ECG electrode, electronic system, Bluetooth module, data transmission module, battery and charging cable, and the battery is a rechargeable battery.



1. Left index finger electrode
2. Right index finger electrode
3. Bluetooth connection indicator
4. Charge indicator
5. Battery recharging port

5. Getting Started

5.1 Package Content

1	Wireless ECG recording box (with MONERR APP)
1	USB charging cable
1	User Manual

5.2 Device Setup Instructions

The wireless ECG recording box comes with a partially charged lithium ion battery so you can start using your device straightaway.

The wireless ECG recording box connects to a compatible smart device via Bluetooth. In order for the device to communicate with the MONERR APP, make sure Bluetooth is enabled on the smart device under Settings.

5.3 Software Installation

On your smart device, download the MONERR APP to use.

For Apple iOS Systems:

1. Go to the Apple App Store.
2. Search for MONERR.
3. Download and Install the MONERR app.

For Android Systems:

1. Go to the Google Play store.
2. Search for MONERR.
3. Download and Install the MONERR app.



6. Operating Instructions

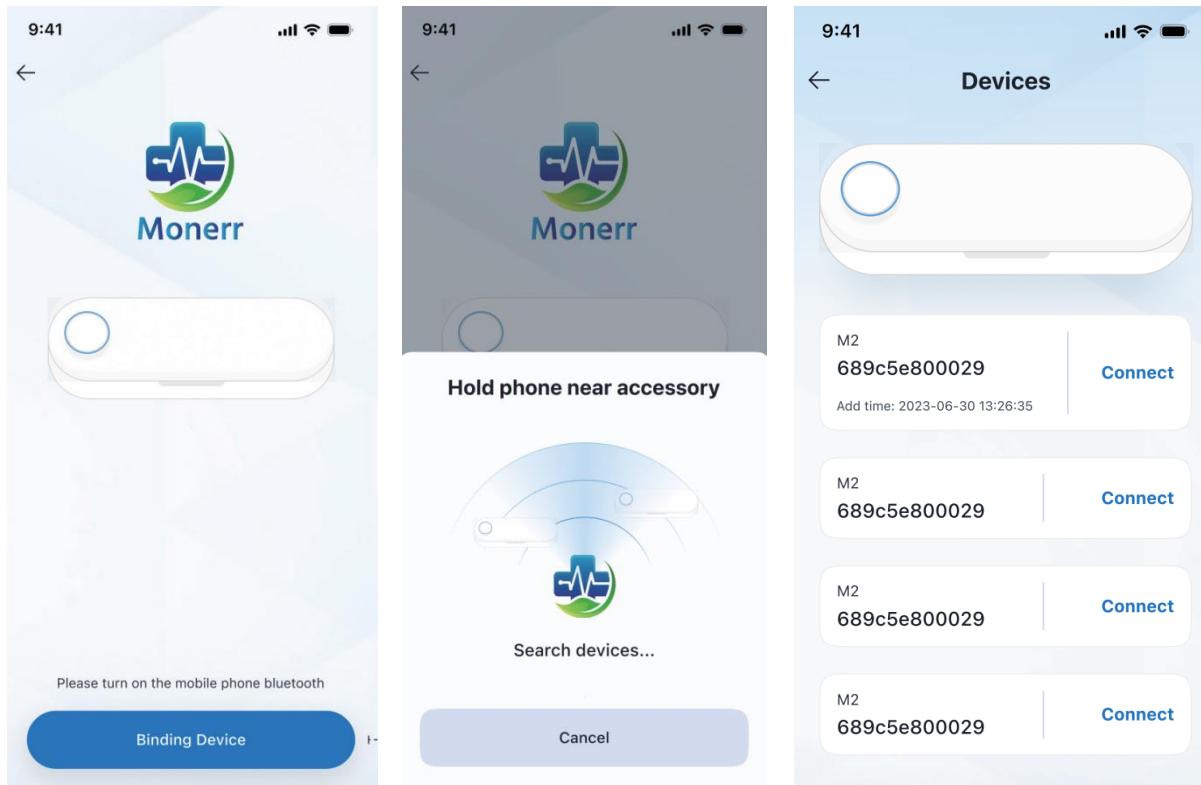
6.1 Create a User and Verify your Email Address

On your mobile device, start the application:

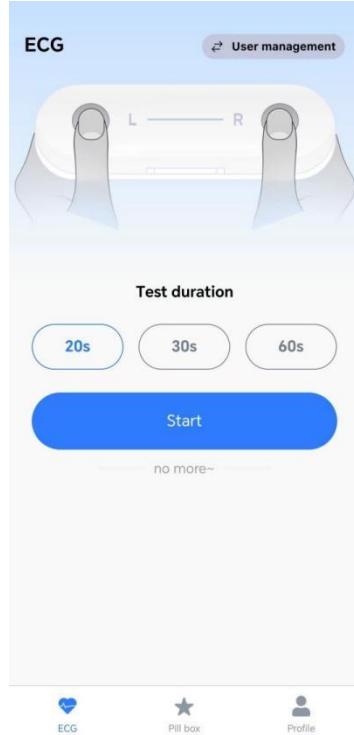
1. When you run the application for the first time, you will be prompted to enter user information. Fill in all the fields.
2. In the MONERR application, click "Verify" to request email verification.
3. A verification email will be sent to your email address. Enter the verification code from the email into the MONERR application to complete registration.

6.2 Recording Your ECG

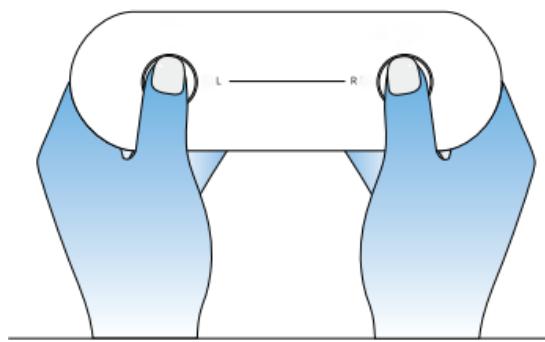
1. Long press the button on ECG recording box for 4 seconds to power on.
2. Press the “Binding Device” button from MONERR app to search the ECG recording box.
3. Select the one you want to connect and click the “Connect” button from MONERR app to connect the device.



4. Click "ECG" button from the bottom of MONERR app to enter the ECG measurement page, select the test duration time (choose one of 20s, 30s or 60s), and click "Start".

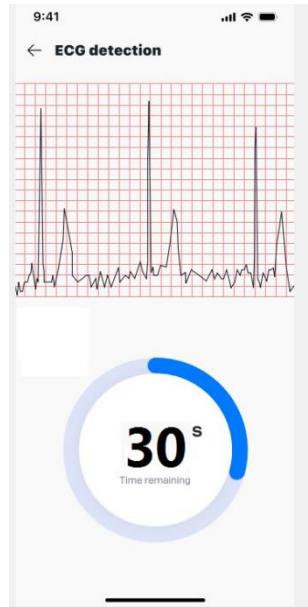


5. Then use your thumbs of both hands to gently grip the metal electrode, leaning hands on a desktop or the thigh. Maintain a relaxed state and do not apply a lot of pressure when holding the ECG device.



6. As soon as it is held, the ECG recording box will automatically connect to the MONERR app on your smart phone. It will show a 5 second countdown before the ECG recording begins.

7. You will be able to see the ECG waveform on the screen of your Smart phone as it is being recorded after the MONERR app has been in the testing. You will only see a screen with a countdown recording timer backwards from the selected test duration time to zero seconds.



- Once recording is complete, the MONERR app will indicate the recording result as following:

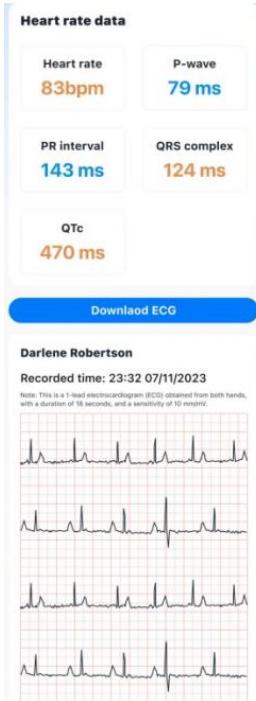


9. Click the middle button “Download ECG” of the result page to go to download your saved ECG recordings.

6.3 Viewing Your ECG Waveform

The collected testing results and historical ECG data records are displayed on this page.

Click on each ECG entry to view detailed ECG data, including single-lead waveforms and heart rate information, P-wave, PR interval, QRS complex and QTc.

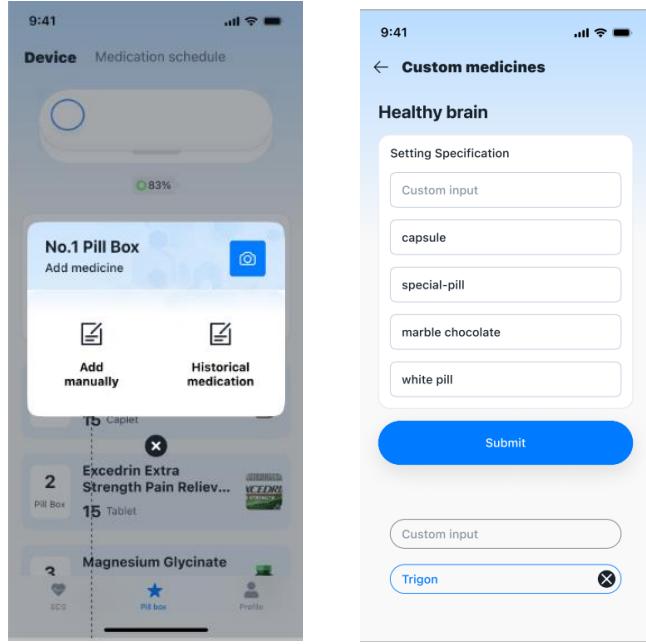


6.4 Medication information Recording

6.4.1 Adding Medications

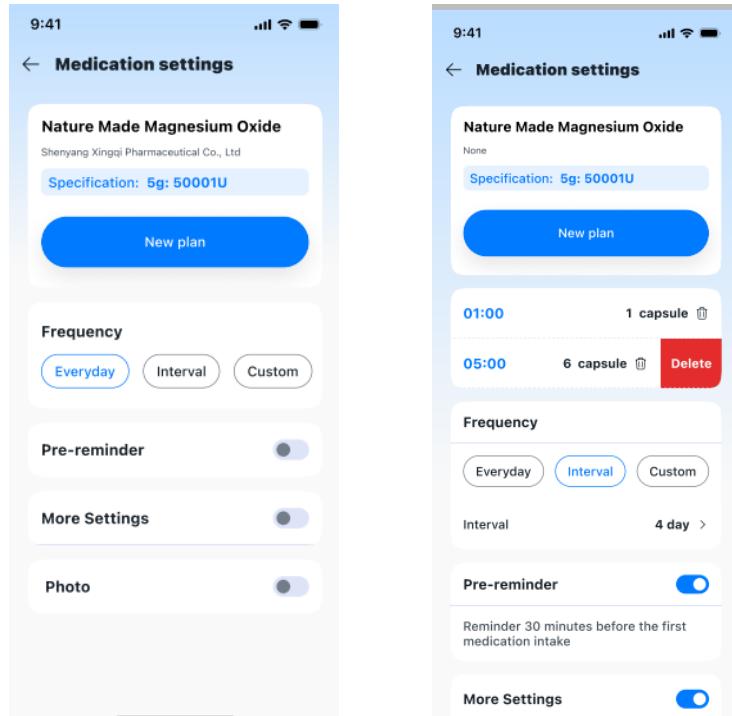
Manually enter the medication name in the MONERR app to add a new medication, or

Quickly select medications from the medication history record.



6.4.2 Medication Reminders

Set reminders in the MONERR app. When it's time to take the medication, the ECG recording box will emit a beep sound to remind the user and record the action.



6.4.3 Viewing Records

View the medication history at any time in the MONERR app.

7. Cleaning and Maintenance

7.1 Cleaning

- Do not open or attempt to repair your ECG recording box by yourself. Only authorized service personnel may repair the device.
- Do not drop the device or subject it to severe impacts. Bending the body can damage the circuitry.
- Do not use solvents to clean your device.
- Use only a soft, dry cloth.

7.2 Maintenance

1. Charge the battery with the certified charging cable provided by Intel love (Tianjin) Medical Device Co., Ltd.
2. Charging the device: please charge the device with dedicated charging cable; charging voltage: DC 5V, charging current: <=550mA.

7.3 Storage

- Keep the device away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in anyplace that is extremely damp or dusty.
- As this device is not waterproof, do not use it or store it at place where fluids such as water can splash onto it. Raindrops, water spray, juice, coffee, steam, perspiration, etc. may also cause a malfunction.
- Keep the device and accessories away from children as the device or accessories could pose a swallowing hazard.

8. Troubleshooting

PROBLEM/ERROR MESSAGE	RESOLUTION
Unable to Power On	Check if the battery is too low.
Bluetooth Not Connected	Ensure your phone's Bluetooth is turned on.
Indicator Light Not On	Verify that the settings are correct. Check if the battery is too low.
No Sound Alerts	Ensure Do Not Disturb mode is not enabled. Verify that the settings are correct. Check if the battery is too low.

9. Manufactured By

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