

Dynamic ECG Earphone Recorder

Model: RN141

User Manual

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RenNuo(Beijing) Bioinformation Science and Technology Co., LTD.

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This manual was prepared in December 2016, and the organizer is RenNuo(Beijing) Bioinformation Science and Technology Co., LTD.

Special reminder: This product should not be used in the state of charging!

1 Brief introduction

Thank you for your purchase and use of Bud Light ·Heart Eye ECG headset, and this manual will help you learn how to use the Bluetooth headset. Before using this product, you should first understand and be familiar with the use of Bluetooth function of your mobile phone or other Bluetooth active devices, such as mobile Bluetooth function.

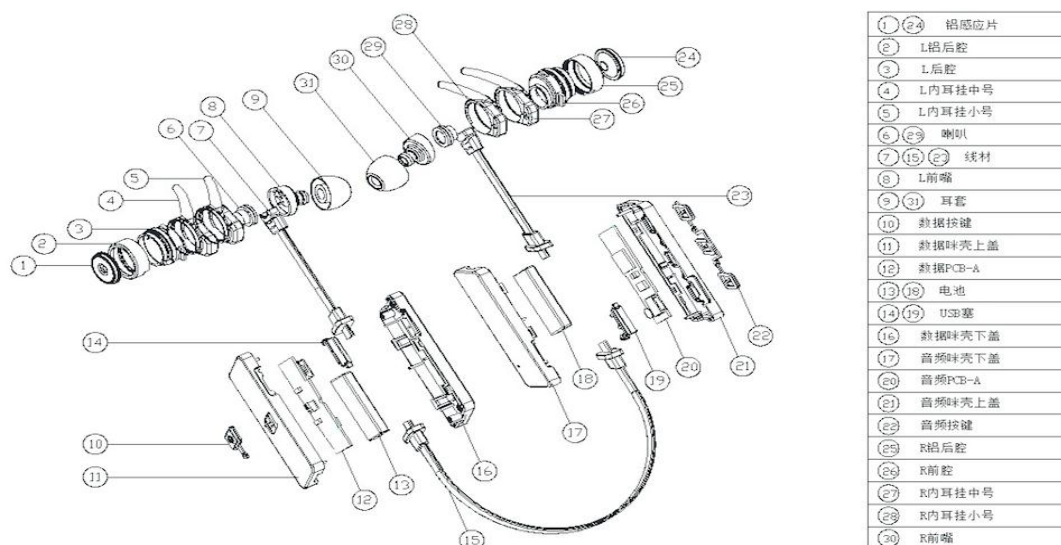
In addition to monitoring your heart always and everywhere, the headset has also Bluetooth headset function.

To use the ECG monitoring function, APP program provided by Rennuo should be installed on the mobile phone, and operating system of the mobile phone that the app will be installed should be Android version 4.4 and above as well as version ios8.0 and above.

In order to ensure the stability and accuracy of the measurement, it is recommended to use silica gel ECG electrode tab.

Advise to add:

- 1, disclose the method for calculating the heart rate
- 2, disclose the method for determining a pause



2 Product description

2.1 Product name

Product name: Dynamic ECG Recorder

2.2 Product model

Product model: RN141

Product naming rules are as follows:

RN—Abbreviation of Rennuo Company

1- Bluetooth communication series of Rennuo Company

14-Generation system of Rennuo Bluetooth

141-Generation system of Rennuo product

The matching APP software of the product is used on the mobile phone, the minimum configuration requirements of the mobile phone are as follows:

IOS Version: Version IOS8.1, support Bluetooth 4.1 protocol;

Andriod Version: Version Andriod4.4, support Bluetooth 4.1 protocol;

2.3 Product specifications

Product specifications: product length: 53cm and electrode diameter of 1.2cm

2.4 Product performance

Single lead type ECG testing and recording, it is mainly used for testing, displaying and storing instant ECG of the user.

Constituent parts of the product: In-ear headset, touch type electrode tab, ECG processing chip, integrated circuit, APP control software of mobile phone.

2.5 Performance index

2.5.1 Working conditions

Ambient temperature: 10℃~45℃; Because the electrode is used for fitting the skin, it can cause discomfort to the skin over 45 degrees centigrade.

Relative humidity: 10%~95% (non-condensing);

Atmospheric pressure range: 700hPa~1060hPa;

Power supply: charging power supply AC220v, charging current and voltage DC 3.5V-5V.

Device circuit board operating voltage 3.7v, current 16MAH, power 0.059W

Transportation environment: -40°C~55°C, Relative humidity: 10%~95%

Storage environment: -40°C~55°C, Relative humidity: 10%~95%

2.5.2 Technical parameter

Name	Headset type ECG recorder
Model	RN141
Channel	Single channel
Technical parameter	Dynamic input range: For superimposed $\pm 300\text{mV}$ DC bias voltage, with the change of the differential mode voltage at the speed of 125mV/s, amplitude modulation of 6mV (when the gain is set to be 10mm/mV), the recorder should have the ability to respond and display. The magnitude of the time-varying output signal is equivalent to the input change of no more than 10%. Input impedance: For the 10Hz sine wave signal, the input impedance should be greater than $10\text{ M}\Omega$. This requirement should be met within the range of $\pm 300\text{mV}$ DC bias voltage. Common mode rejection: For the sinusoidal signal under the network power supply frequency, the common mode rejection should be at least 60dB, for the signal under 2 times network power supply frequency, the common mode rejection should be at least 45dB. Systematic noise: When the input terminals connect each patient's electrode in series through a resistance and capacitance network in parallel including $51\text{k}\Omega$ resistor and a 47nF capacitor, the internal noise equivalent to the input should not exceed $50\mu\text{V}$ (peak - valley value) within 10s at random. Gain accuracy: When the gain is set to be 10mm/mV, the test signal of the output signal equivalent to input, the maximum amplitude error is $\pm 10\%$.

	Frequency response: a) Applying a square wave of 3 mV and 100ms to a recorder, the bias between the baseline after the pulse appears and the baseline before the pulse appears should not exceed 0.1 mV, and the slope after the pulse end point should be not more than 0.3 mV/s, the overshoot of the pulse edge should be less than 10%; b) For the sinusoidal signal with a frequency of 0.67Hz~40Hz, the response magnitude should be between 140% and 70% of the magnitude at 5Hz (-3dB~3 dB); c) The response amplitude of the 1.5mV 40ms triangular wave pulse group for simulating a series of R wave narrowband should be between 60%~110% of the response amplitude at 1.5mV 200ms triangular wave pulse group. Minimum detection signal: When the operating speed is set to 25mm/s and the gain is set to 10mm/mV, after a sinusoidal signal of 10Hz, 50μV(peak - Valley value) is applied, there should be an apparently visible deflection. Gain stability: After the device is powered on for 1min, the gain change in 3min cannot exceed 3% (under stable ambient conditions). Heart rate measurement range: Heart rate display range: 30bpm~200bpm, error: ±1bpm
Measurement time setting	1. 30s 2. 180s
Product life	5 Years
Typical operation time or number of procedures of battery	Battery endurance of about 8 hours
Typical service life of	5 years

the battery	
the time required for the equipment to warm from the minimum storage temperature between uses until it is ready for intended use	7 min
the time required for the equipment to cool from the maximum storage temperature between uses until it is ready for intended use	3 min

2.5.3 Panel controls and switches



2.5.4 User's electrode and lead

Lead naming	User's electrode connection mark	Colour codes	The position of the human body surface
I Lead	L	L indicates positive	Left thumb

		electrode, and there is no color difference	
	R	R indicates negative electrode, and there is no color difference.	Right thumb
II Lead	L	L indicates positive electrode, and there is no color difference	Left ankle
	R	R indicates negative electrode, and there is no color difference.	Right thumb
V4 Lead	L	L indicates positive electrode, and there is no color difference	The position of one finger below the left breast
	R	R indicates negative electrode, and there is no color difference.	Right thumb

2.6 Precautions for use

1. Users with pacemakers should use under the guidance of the doctor.
2. Please use in the environment away from the electromagnetic interference.

warning: No modification of this equipment is allowed

For example: check whether the boot is running properly before testing.

The equipment can work normally only when powered on

1. To prevent infants and young children eating earphone parts such as ear glue cap
2. This device should be repaired by specialized persons, otherwise it will lead to insecurity.
3. The device is built-in battery, the device, keep it away from high temperature or direct sunlight.
4. It is recommended to replace the electrode after 5 years of use.
5. Because of the small size of the product, it is recommended to be stored in a place where children can not reach.
6. The device is with precise internal circuit, keep it away from other conductive parts in case of an accident.

2.7 Safe use

Safe use: Waterproof, anti exposure, away from fire source

Use range: Charging power supply 220V, charging current and voltage 3.5v-5V

Device circuit board working voltage 3.7V, current 16MAH and power 0.059W

Method to determine state of internal electrical power source: In order to avoid inaccurate measurements, recommended to charge the device when it is continuously used for more than 6 hours or idle for some time,

2.8 Accessories list

In-ear rubber caps: 3 sets, including a set of large, medium and small rubber caps

A piece of charging (data USB) wire

A headset storage bag

A copy of manual

A pair of medical silica gel tabs

3 Production enterprise information

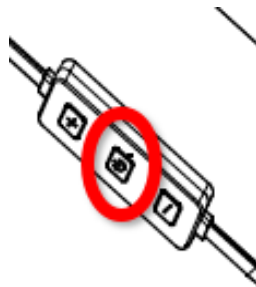
Production enterprise: RenNuo(Beijing) Bioinformation Science and Technology Co., LTD.

Add: No.18, Zhong Ding Road, Daxing District, Beijing, China

Tel: 010-81285656

3 General function

3.1 Boot



Power supply key: The condition of power off, long press the power supply key for 3s, the power is turned on. And during charging, the indicating light is always lighted.

3.2 Shutdown

Under the state of the power supply being on, long press the power supply key for 3s, the power is turned off. And the indicating light goes out.

3.3 Pairing

After the headset is booting, the green indicating light is always lighted, and after the mobile Bluetooth is on, pairing should be made with the headset, and when the green indicating light of headset flickers, it indicates the pairing is successful; Audio Bluetooth code: RNY141; ECG Bluetooth code: RNS141.

4 Listening to music

4.1 Volume control

The volume can be adjusted through adjusting “+” and “-” on the headset wire, press the “+” to increase the volume and press the “-” to reduce the volume;

4.2 Changing song

The song can be changed through adjusting “+” and “-”.

5 ECG monitoring

5.1 Use of monitoring



The ECG can be measured through the skin contacting two electrode tabs on the back of the headset, which can be measured by 12 lead channels;

6 ECG Functional Use Instructions

6.1 APP use instructions

Choose to download the IOS version or Andriod version according to the operating system of your own mobile phone, and after the software is downloaded successfully, open the software, and connect the headset through the phone's Bluetooth. After the connection is successful, the headset will give voice prompts.

6.1.1 Registration

After you register, you can use the headset ECG testing function. Through entering your mobile phone number and setting login password, you can register as a member of Rennuo, thus to enjoy the medical services provided by Rennuo.

Please be sure to use the real mobile phone number to register, otherwise you will not be able to enjoy the professional medical service of Rennuo.

Registration steps are as follows:

1. Open APP, enter your mobile phone number and password, and click 'next step'.



< 注册 登录

注册心眼，记录您的心率数据，
我们的医学专家会为您提供专业的帮助。

输入您的手机

输入您的密码

重复输入密码

下一步

2. Fill in name, gender, body height, weight, date of birth, emergency contact person and other personal data to achieve more accurate feedback data, and after clicking “complete”, the registration will be successful.



< 注册 登录

您的真实姓名

男性 女性

175cm

70kg

2015 / 12 / 05

输入您的联系人

输入您的联系人电话

完成

6.1.2 Login

You can use all the ECG functions of the headset after logging in.

Operation steps:

After entering the mobile phone number and password filled in during registration, click “Login”, and login will be completed.

respectively pasted to the radial artery of the wrist and the electrode is buckled onto the tab), the left hand is pasted to “L” end and the right hand is pasted to “R” end.

The measurement method is as follows: open the app, choose the measuring position, then connect the ECG Bluetooth devices, and after connecting, the measurement can be made.

When selecting the measurement at the lead position in app, wipe the two thumbs of the left hand and the right hand clean, and then respective paste them on the left and right electrode tabs of the headset, and then click “start” and start measurement;

Operation steps:

1. Open mobile Bluetooth and headset Bluetooth.
2. Open the APP, click and select the measurement, and then click and select I lead measurement, and select the measurement time (30s or 3min) according to screen prompts,



3. APP will automatically detect the headset Bluetooth, and the headset Bluetooth should be selected according to the prompts, and APP enters the waiting state for detection.



4. Wipe the right and left thumbs clean respectively and paste onto the electrode tab of the headset (It is suggested that the silica gel electrode tabs should be respectively pasted to the radial artery of the wrists and the electrode is buckled onto the tab), the left hand is pasted onto “L” end and the right hand is pasted onto “R” end.

5. APP automatically start measuring, and at the time, please do not move your hands, and wait for the end of the measurement automatically.



6. After the end of the measurement, APP will automatically display the measurement result,

as the figure below.

7. At the time, you can choose your condition and feeling, and input the remarks, for future use of inquiry.



8. If dissatisfied with the measurement, you can click and select “return”, and repeat the steps 2 - 6 in accordance with the above steps, and if you are satisfied with the measurement, please click and select “save”, the measurement data will be stored on your mobile phone.

II. II Lead measurement

For the measurement at the position, it is OK after right thumb is pasted to the electrode tabs of headset, the left ankle is pasted to “L” end and the right hand is pasted to “R” end.

The measurement method is as follows: open the app, choose the measuring position, then connect the ECG Bluetooth devices, and after connecting, the measurement can be made.

The position of lead is on the body, and through pasting the tabs provided by Rennuo onto the body, the electrode tabs on both ends of the headset are respectively buckled onto the tabs, to measure the ECG.

The measurement method is the same as above:



III. V4 Lead

For the measurement at the position, it is OK after right thumb is pasted to the electrode tab of headset, the left chest is pasted to “L” end (one cun below the breast) and the right hand is pasted to “R” end.

The measurement method is as follows: open the app, choose the measuring position, then connect the ECG Bluetooth devices, and after connecting, the measurement can be made.



IV. Position of doctor's advice

12 Lead ECG can overall judge the user's physiological indexes of the heart, and when the doctor needs ECG of other lead positions, the user can follow the doctor's advice to make measurement at other positions.

6.1.4 Inquiry

You can inquiry the measurement data saved before.

Operating methods:

1. Open APP and click and select "Record".



2. Here, you can find all the saved measurement records before. After clicking and selecting the record to inquiry, you can look up the history testing data.



3. In case you want to delete a history measurement record, you can swipe to the left on one record, and then the delete button will appear, and then it is OK after clicking and selecting “Record delete”.



4. In case you want to delete several history records, you can click and select “Multiselect”,

and then select the records you want to delete, and then it is OK after clicking and selecting “Record delete”.

近 10 次的测量结果			平均值: 74
✓	常规测量 2016-12-21 08:44:25	100	bmp
✓	常规测量 2016-12-20 22:35:13	101	bmp
✓	常规测量 2016-12-20 22:02:27	121	bmp
✓	静息心率 2016-12-20 19:55:57	200	bmp
✓	常规测量 2016-12-20 15:41:40	081	bmp
✓	常规测量 2016-12-20 15:25:09	060	bmp
✓	常规测量 2016-12-20 15:19:30	080	bmp
⊗ 记录删除			

6.1.5 Feedback

Open APP and click and select “Record”, and in the history record, select the records needing feedback, swipe to the left and it is OK after clicking “Need feedback”.

6.1.6 Setting

Here, you can inquiry your account information and set up APP.



7 Common problems

1: What does the APP do?

Reply: The APP is the software to make ECG measurement and display matching your ECG headset, and transmit the detected ECG to the doctors at the backstage, thus to obtaining the diagnostic suggestions.

2: Why do you need to fill in the registration information?

Reply: the correct diagnosis of ECG data needs the evidence of the information.

3: How to use the installed APP to make ECG measurement?

Reply: Scan the two-dimensional code on the certificate in accordance with the system of your mobile phone (IOS or Android), download and install according to the prompts. After the successful installation, registration should be made, and please fill in your personal information truthfully; and login can be made after the registration is successful.

4: How to connect?

Reply: Open the headset power supply, and the indicating light will flicker. Open mobile setting--Bluetooth connection. The audio communication Bluetooth code is RNY141, and after connection, the headset communication function can be used. During using ECG system, click APP icon "Bud Light Heart Eye" to connect RNS141, and after the "success" is displayed, the ECG measurement can be made according to the page prompts.

5: Why there are four measurement selections?

Reply: ECG is the golden standard for judging heart disease. 12 Lead ECG machine is used in the medical institutions, and ECG of various leads have different judging meaning for judging different pathological phenomena. The device is provided with 3 fixed measuring positions according to different situations to facilitate user's use. In special conditions, doctors need to know the ECG at other lead positions, and you can monitor ECG according to the doctor's advice position drawing, to be conducive to a comprehensive and accurate diagnosis of doctors.

6: How to do if it can't be connected?

- Reply: a. Close the headset ECG switch, and re-open it;
b. After exit from the measurement page, re-click the "Measurement".
c. If the electric quantity of battery is low, please re-connect after charging.
d. Inquiry whether the ECG headset is binding with your mobile phone.

7: Why the binding is needed?

Reply: The heart disease has a transient characteristic, and it is essential for diagnosis of the disease to rapidly capture the effective ECG. In order to facilitate users to quickly use, the headset ECG is connected with the mobile phone, and mobile phone APP can only connect with the ECG headset, and according to the design, from opening the power switch of the headset to clicking "Bud Light Heart Eye" icon to enter "measurement" page, it only takes 15s to detect and record ECG data.

8: Why the long time ECG record is needed?

Reply: There are changes in cardiac activity. One ECG is valuable, but the comparison of historical information is more important. Through comparison and analysis of data, the future

can be predicted.

9: How to do if there is electromyographical interference?

Reply: For the R end, please select measurement at the fossa cubitalis place or right scapula place.

Production enterprise information

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Tel: 010-81285656

After-sales services Tel: (010) 81285656 to customer service department

Signs & Symbols

	Follow operating instructions
	Type CF applied part
	Indicates the unit manufacturer, including manufacturer's name and address
	Disposal note for electronic devices
IP22	the IP classification
SN	Production license Number
	Date of manufacture
	European participants information

Daily Cleaning and Maintenance

Wipe the device with a clean cloth after being used for a period of time, then stored in a dry place.

The Use and Maintenance of Battery

when the battery is defective, contact our after - sales service for the replacement. it may damage the product if person without any skills or being trained replace the battery.

Recycling of products

The product is medical device, prohibited to carelessly disposed. Products can be handed over to local dealer or local medical device recycling agency for disposal after it scrapped.

FCC Statement

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.

FCC RF Exposure Information and Statement

Use of other accessories may not ensure compliance with FCC RF exposure guidelines.