

EZYPRO ECG Recorder INSTRUCTIONS FOR USE

SKU: UG02U0R

Copyright notice

Intellectual property rights arising out of any content in this document is owned by Sigknow Biomedical or has been licensed to it by the owners of the intellectual property rights.



Please read this manual carefully before using the device.

Dear Customer, thank you very much for choosing EZYPRO. This manual is written and edited by Sigknow Biomedical Co., Ltd.; all rights reserved. Reproduction, alteration or deletion is NOT allowed without permission.

Security check statements

This person is wearing EZYPRO ECG Recorder prescribed by his/her physician. The device is adhered to the patient's chest to record the heart rhythms. It can only be removed with the permission of his/her physician. If you have any questions, please contact his/her healthcare provider.

Sigknow Biomedical preserves the final right to explain the contents of the manual and does not have any obligation to track updated version of the manual or update the contents accordingly.

Table of Content

About this device	3
 Caution	3
 Important information	3
Product introduction	5
Accessories introduction	6
Measuring principles	7
 Notice for use	7
LED Light Guide	10
Applying Steps	12
Q & A	28
Specifications	30
EMC Declaration	31
Symbol Explanation	34
FCC Compliance Statement	35

About this device

Model: UG02

SKU: UG02U0R

Intended Use

EZYPRO ECG Recorder is a prescription-only, single-patient-use, continuously recording cardiac rhythm recorder that can be worn up to 14 days each time through recharge. It is indicated for use on patients who are 18 years old or older and those who might suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue or anxiety.



Caution

1. The device is applicable to any adult who is 18 or older. Pregnant women, hyperhidrosis patients, or someone who is wearing a pacemaker aren't allowed to wear this device due to medical reasons.
2. The device is not for diagnostic purpose and doesn't alarm for life-supporting purpose. It is not intended to use on critical care patients.
3. Do not use this device if the patients have had symptomatic episodes, which could result in immediate health danger to the patients.
4. Do not use this device on patients who have known history of life-threatening arrhythmias.
5. People who are allergic to adhesive, hydrogel, or have a family history of adhesive allergy, do not use this device.
6. Do not apply this device on any place on the skin that has wounds. People with sensitive skin or other skin conditions may have the result of skin redness, swollen, or allergies when using this device. Consult with your doctor before using this device.
7. This device must be removed before AED rescue. During the use of this device, MRI, CT, or neurostimulation therapy is inadvisable.



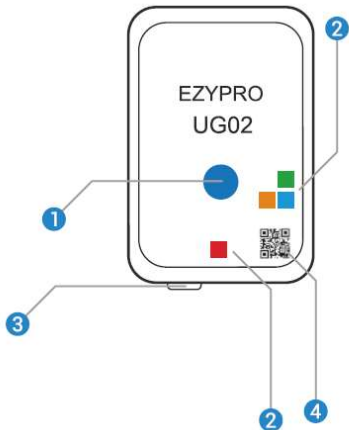
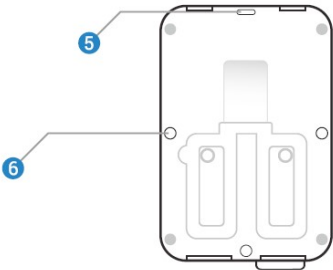
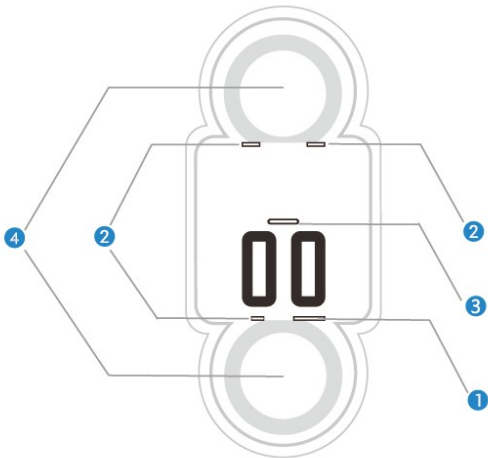
Important information

1. Follow doctor's directions when using this device. The recorder works with the patch. Patch's service life is up to maximum of 14 days. The wearing time could be shortened based on the different conditions of the skin or inappropriate uses of the device.
2. This is a medical device that should always be used under doctor's instructions or medical professionals' assistances.
3. Please stop using this device immediately and consult with a doctor when any redness, swelling, severe irritation, or allergic reaction (such as hives) occurs under the use of this device.

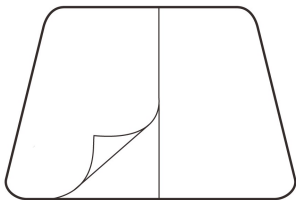
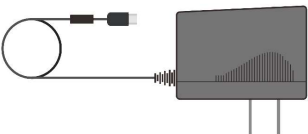
4. The recording from the device can only be used as a reference for the physician to make further diagnoses based on the medical condition of the patient. It should not be used directly as a factor in clinical decision.
5. This device shouldn't be worn when bathing or exercising, due to the water and sweat that can cause the patch to peel off. Underwater activities are not allowed when wearing this device.
6. There are temperature and humidity limitations for this device. If exposed to high temperature or high humidity, the adhesive performance of the device may be affected, causing the device to fall off.
7. The recorder should be charged before using.
8. Patch has an expiration date. Use of expired patch may cause a degradation of ECG signal quality or adherence capability.
9. During the first 24 hours after applying the device on one's body, make sure the patch is well-stuck to the body and avoid all kinds of activities that will cause sweating or water around the patch. After the first 24 hours, you could resume normal activities and moderate exercises. Do not take a bath or exercise within the first 2 hours after applying the device.
10. The patch is for one time use only.
11. This device is delicate and needs to be used with care. Avoid dropping or any kinds of actions that may cause damages to the device.
12. Do not put this device in an autoclave or gas sterilizer (such as EO, formaldehyde, high concentration ozone, etc.).
13. Avoid being in a strong electromagnetic environment while wearing the device, since it may affect the accuracy of the measurement from the device.
14. Do not use benzene, benzine, or any other volatile substance to clean the device and electrode contacts.
15. This device does not require regular maintenance or calibration. If need to repair, please contact the local distributor and do not disassemble the device.

Product introduction

EZYPRO ECG Recorder is a single-lead ECG recorder that can transfer the recorded ECG signal to another device powered by Android device through Bluetooth while wearing it. The duration and other basic operational parameters of the recorder are allowed to prescribe for varied needs.

Front side (1) Start button/ Event trigger button (2) LED lights (green/red/orang/blue) (3) USB slot (4) QR code	
Reverse side (5) Cartridge groove (6) Cylinder	
SIGKNOW ECG Patch Model: UG02 (1) Bigger bordered latch (2) Smaller bordered latches (3) Middle latch (4) Electrodes (This patch need to be purchased separately.)	

Accessories introduction

Waterproof plug		The waterproof plug is a rubber plug of Micro USB port to avoid liquids flowing into the recorder. Need to attach or detach the plug by a tweezer.
Overlay tape (Exclude in this product)		The overlay tape is a medical nonwoven tape to paste on the patch for improving the floating situation.
Micro USB cable		The Micro USB cable is a one-meter long cable to contact the recorder and PC.
GOE Switching Power Supply 		GOE Switching Power Supply is an adapter complied with IEC 60601-1 3.1, used to charge the recorder. Input: 100-240V~0.2A 60/50Hz Output: 5V 1200mA 6W Max

Product features

1. This device can record up to 14 days of cardiac rhythm. Wearing duration of the device is adjustable based on different needs of the patient.
2. Micro SD card is being used to store data signal in this device which can be downloaded for further analysis on our software.
3. This device is lightweight, wire free, and easy to carry around.
4. Patients can make notes when experiencing symptomatic episodes by pressing the blue button on the device; physician can later look back at the data and see the notes patient made and use it in the diagnosis.
5. This device is reusable by charging the battery of it and changing the patch.
6. This device won't interfere your daily routine or any activities.

Measuring principles

ECG recorder is to measure every tiny waveform derived from electrical pulse of cardiac cells by using electrodes on patient's body surface. The electrical currents can be detected from multiple surfaces of the patient's chest and limbs, and the signals will be obtained based on relative positions of the electrodes on the skin. (Reference: Berbari, E. J. "Principles of Electrocardiography." The Biomedical Engineering Handbook: Second Edition, Edited by Joseph D. Bronzino, CRC Press LLC, 2000.)

Notice for use

1. Please use the device in the recommended operating environment indicated in the section "Product Specifications".
2. Sigknow Biomedical Co., Ltd. shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, or failure to operate the device according to instructions.
3. Wear the device according to the physician prescription. If need to analyze ECG data, please use Sigknow analytical software (**this product does not include**).
4. **SIGKNOW ECG patch is combined used with EZYPRO.**
 - 4.1. Patch is for single use and needs to be disposed after use.
 - 4.2. Confirm the applying area before attaching. (refer to the "Apply Steps" section).
Reattaching the patch will affect the measurement performance or cannot to measure.
 - 4.3. Do not touch electrodes with fingers when operating.
5. The device has temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to fall off.
6. The recorder shall be charged well before using.
7. The patch has a shelf-life date. Use of expired patch may cause a degradation of ECG signal quality or adherence capability.
8. The patch needs 24 hours to stick well to your skin, please avoid any activities which cause sweating during this period. After the first 24 hours, you could resume normal activities and moderate exercise. Do not take a bath or exercise within 2 hours after attaching the device, so as not to affect the adhesion of the patch.
9. The patch is only for one-time use.
10. Daily activities can be maintained during wearing duration. Dress or undress gently to avoid striking the device.
11. Staying in cool and comfortable environments is recommended. For example, the 25°C air-conditioned rooms.
12. Please avoid engaging in intense and sweaty activities. A large amount of sweat on the surface may cause the device to slip, the poor stickiness of the patch, affect the quality of the signal measurement, or the device may fall off and shorten the wearing duration.

13. The device is waterproof. It allows shower during the duration, but not bathing, steam bathing, swimming, diving and other underwater activities.
 - 13.1. Shorten the shower time and the water should not be too hot.
 - 13.2. Avoid flushing the device directly with water and keep soaps away from it. When wiping the chest, please dry the water by pressing; when wiping other body places, use one hand to fix the device.
 - 13.3. If the patch surface gets wet, let it dry naturally. Do not remove them directly.
14. When symptoms occur such as palpitation, short of breath, dizziness, vertigo, fatigue, anxiety or aggressive, press the blue button on the device to mark the event and fill out a page of "Button Press Log". If the discomfort persists or worsens, seek medical attention immediately.
15. If the patch edge lifts up, run fingers over the entire surface area for 2 minutes to smooth out any "wrinkles". If the floating is serious or wearing more than 7 days, use the overlay tap directly.
16. **Use the medical grade adapter specified by this product to charge.**
 - 16.1. Do not use another unqualified charger. Wrong voltage input of charging will damage the battery and interrupt recording.
 - 16.2. The plug of the charger may not be suitable for your area. Please install the conversion socket head to suit the local area.
 - 16.3. Do not charge while wearing the device. Avoid leakage or excessive temperature during charging, resulting in skin burns.
 - 16.4. If the USB socket is wet, please wait it dry to avoid short circuit.
 - 16.5. The recorder is needed to charge before use or for long term storage. There's no need to replace the battery.
17. Battery can be recharged at 500 times. It might degrade earlier due to charging, operation, or storage out of the specified temperature range, reference to the section "Specifications". The device might not last for 14 days of recording while battery is degraded.
18. Be careful of children to inhale or swallow the waterproof plug of the device.
19. The App "EZY iSee" is for reviewing the ECG quality while wearing but doesn't provide analysis or diagnosis functions. It is only for the medical institution.
 - 19.1. The opposite Android platform shall install "EZY iSee" and keep the distance within 3 meters. Total transmission time is 30 minutes and the remaining time could be found on screen in the App.
 - 19.2. Do not remove the device from body while transferring signal.
 - 19.3. EZY iSee shows the patient's heart rate during transferring ECG signals. The heart rate is determined by previous 8 R-R interval (RRI). The computing details were showed as the following formula.

$$RR_{mean} = \frac{RR_n + RR_{n-1} + \dots + RR_{n-7}}{8} \text{ (sec)}$$

$$\text{Heart rate} = \frac{60 \text{ sec}}{RR_{mean}}$$

Where $RR_n, RR_{n-1}, \dots, RR_{n-7}$ were previous 8 RRI.

- 19.4. Do not use Bluetooth bracelets or other Bluetooth-enabled electronic products at the same time, it might cause signal interference or transmission delay.
20. The program “UG02 setting tool” is used to set up operational parameters of the device, such like recording time, UTC time & patient ID. It is only for the medical institution.

LED Light Guide

The light indication is only related to the status of the recorder and does not involve the health status of the user.

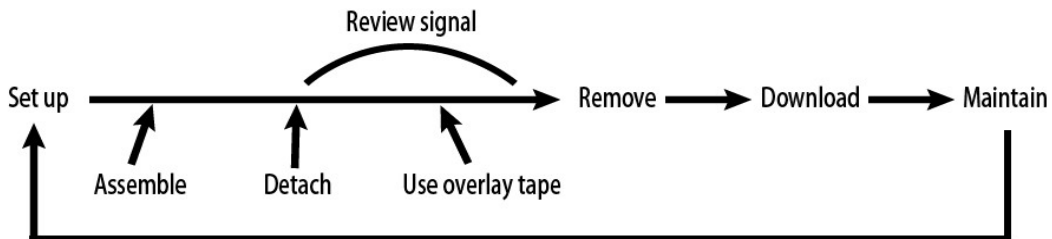
General Situation	While Power On successfully, Green LED lights up for 30 seconds. 	Power on successfully.
	While Power On, Orange LED flashes 5 times and then go down. 	Device doesn't power on due to lead off. Please keeps pressing the patch for 2 minutes (especially frontside of electrodes) and repeat power on.
	While blue button is pressed after Power On, Green LED flashes for 3 times. 	An event has been marked in the recording data.
	While Lead Off, Orange LED flahes. 	Lead Off event happens. Please keeps pressing the patch for 2 minutes (especially frontside of electrodes) until leading on.
	Blue button is long pressed for 3 seconds to enable Bluetooth. Blue LED flashes twice with a gap repeatedly. 	Bluetooth enabled successfully. If the Bluetooth link has not set up within 2 minutes, the Blue LEDs will go out and the device will disable Bluetooth.
	Blue LED flahes slowly during data transferring. 	The device is sending out ECG to another Bluetooth enabled device.
	While using the setting tool to format the internal ECG recordings.Blue LED flahes slowly during processing. 	Status indicator for data processing while formating. After job done, the Blue LED stop flashing and goes out.
	Green LED flashes while charging.	Charging indicator.

		
	Green LED lights up continuously while charging. 	Charging complete indicator.
Abnormal Situatoin	In Power On stage, Red LED lights up for 10 seconds and then goes off. 	Hardware failure detected. Please consult with your local distributor.
	In Power On stage, Green and Red LEDs light up together for 10 seconds, then go off.  	Device detects that there is already an ECG recording inside. User interruption to erase the existing file is required.
	In Power On stage, Red and Orange LEDs light up together for 10 seconds and then go off.  	Device Low Battery Indicator (Battery often less than 15%). Intended to use can't be achieved. Device shall be charged.
	During wearing the device, Red LED flahes. 	Hardware failure. Please consult your local distributor.
	During charging, Red and Green LEDs flashes ro lights up together.  	Hardware failure. Please consult your local distributor.
	During charging, RED LED lights up 	Charging function might fail to work or operate correctly. Please consult your local distributor.

Applying Steps

PROCESS FLOW CHART

Follow these steps to use EZYPRO ECG recorder. Start from setting the device.



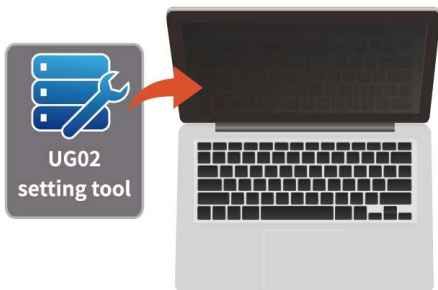
HOW TO SET UP DEVICE?

STEP1 Install software

Please accessed this URL: <https://tinyurl.com/y67u4ywp> to install the program “UG02 setting tool” in PC.

Basic requirement of hardware

- System: Window 7/10 , 64bit
- CPU: Intel i5 or above
- RAM: 2GB or above
- Peripherals: keyboard and mouse

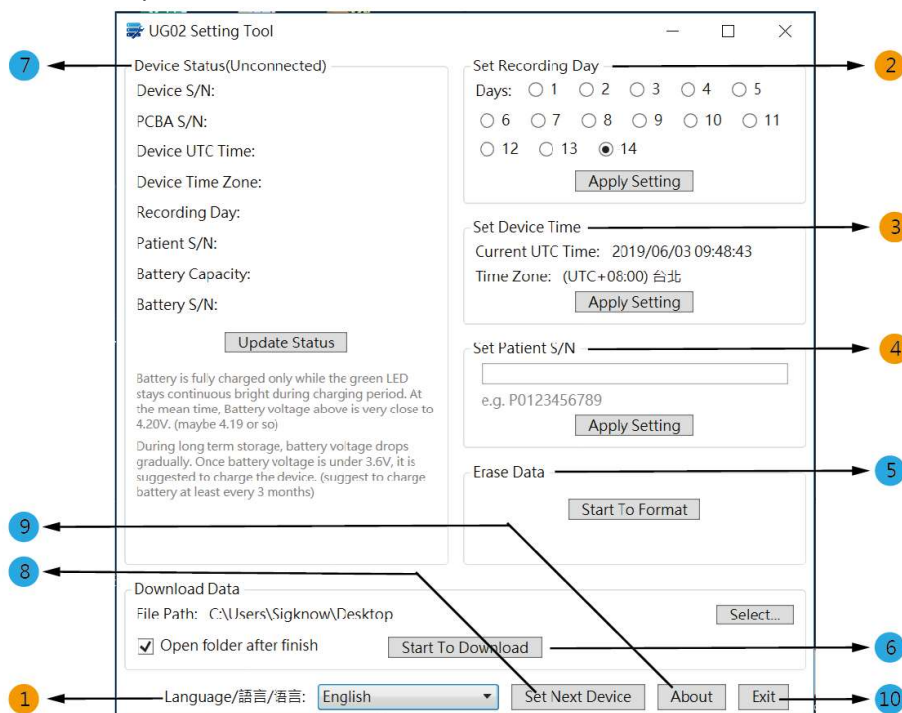


STEP2 Set up

- Please use the Micro USB connector to connect the device and the PC. If the waterproof plug is already attached on the device, please remove it first by the tweezer. After setup, put the waterproof back to the device.
- During setup, please maintain the device connecting to the PC.



- Click the “UG02 setting tool” icon and active. Main screen as shown.
- If it’s shown the low battery on “Device Statues”, please charge first.
- At the first time to set up, please complete the first (1) to the fourth (4) item. Click” Apply Setting” to complete each item.



item	function	Functional instruction
(1)	Language	Click the drop-down menu to choose language.
(2)	Set recording days	Set recording days from 1 day to 14 days.
(3)	Set device time	Set the recorder internal time in UTC (Coordinated Universal Time). When recording ECG signal, it will be based on this time.
(4)	Set patient S/N	Set the patient S/N for tracking, it's also shown as filename of ECG data. Patient S/N is up to 11 yards composed of numbers, letters and allowed some special characters.
(5)	Erase data	Format the recorder. All stored ECG data will be erased and CAN'T BE UNDO. If there is no data, it can be not performed.
(6)	Download	Download ECG data to PC.
(7)	Device status	Shows the recorder current status and will NOT be automatically updated. Press the button "Update Status" to get the most current device status.
(8)	Set next device	Click and a window pops up, follow the on-screen instruction to set next device.
(9)	About	Information about the program version and copyright announcement.
(10)	Exit	Exit the program

- "Device Status" will automatically if re-plug the USB wire during connection..
- Be careful to click "Start to Format", all data in the recorder will be erased and can't be undo.
- After setup, disconnect the ECG recorder from the PC.

HOW TO ASSEMBLE ACCESSORIES?

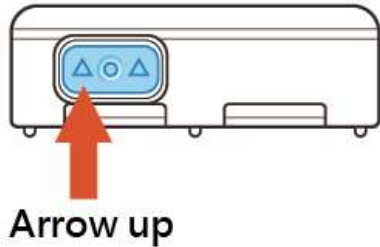
Assemble accessories to the recorder, follow this sequence:

(1) Waterproof plug and (2) Patch.

STEP1 Assemble Waterproof plug

Assemble the waterproof plug to the recorder USB slot.

Be aware that the direction of arrow on the plug must be upward (directing to the blue button).

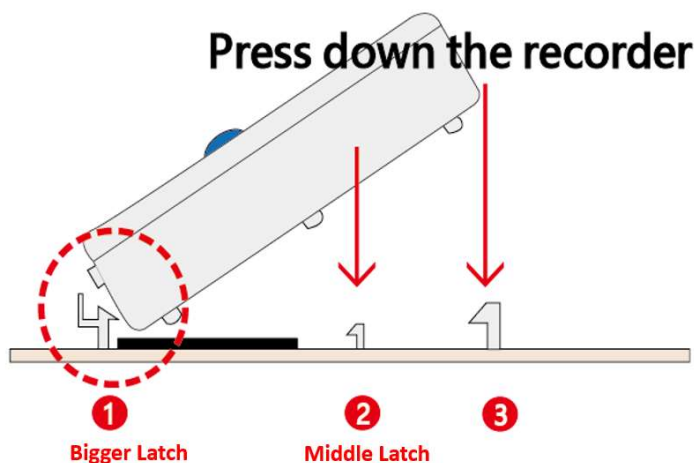


STEP2 Assemble Patch

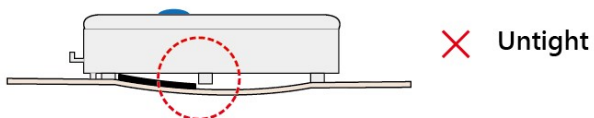
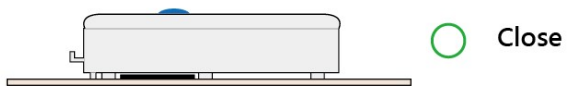
Assemble the patch to the recorder.

Check the direction of the patch must aim to the recorder.

- (1) Align the recorder base to the BIGGER boarded latch of the patch.
- (2) Press down and fasten the middle latch of the patch. **PRESS the MIDDLE side of upper case** to make sure the middle latch installed correctly. It will make a crunch sound. Be aware not to touch the blue button when pressing down.
- (3) Press another side and fasten the smaller boarded latch of the patch. It will make another crunch sound. Then, complete assembly.



Note that there should be no gap between the patch and the recorder, especially the **MIDDLE** latch.

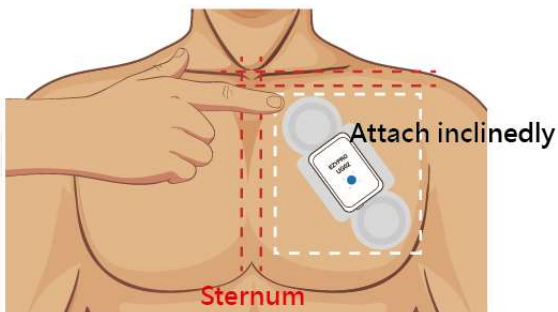


HOW TO ATTACH DEVICE?

STEP 1 Confirm position

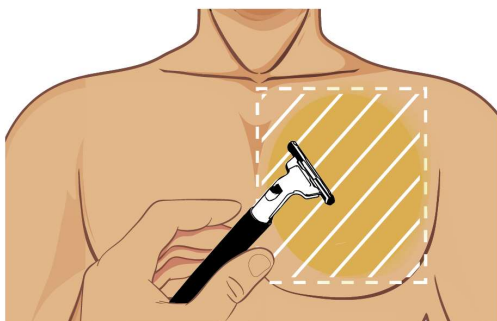
Hold the device as shown, aim the front to the meeting place of the sternum and the one-finger below left collarbone. (Device is attached inclinedly.)

The rectangle is the area that should be cleaned before adhering.



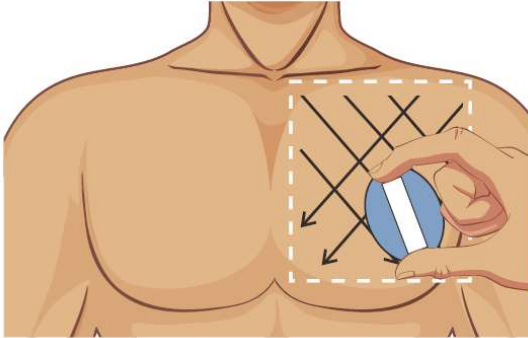
STEP 2 Shave

Use the razor to shave hairs in the rectangle area carefully. (Skip this step if no chest hair.)



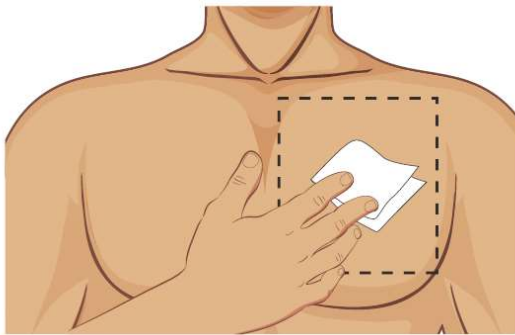
STEP 3 Abrade

Use the abrader to cross stroke the skin in the rectangle area for 10 times.



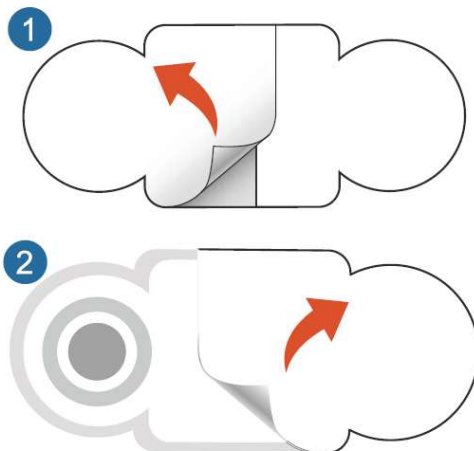
STEP 4 Clean

Use the alcohol pad to wipe the abraded skin. Let dry for 2 minutes.



STEP 5 Remove the paper covering of Patch

Remove the white paper covering on the bottom of the patch and prepare to attach on the chest. Be aware not to touch electrodes.

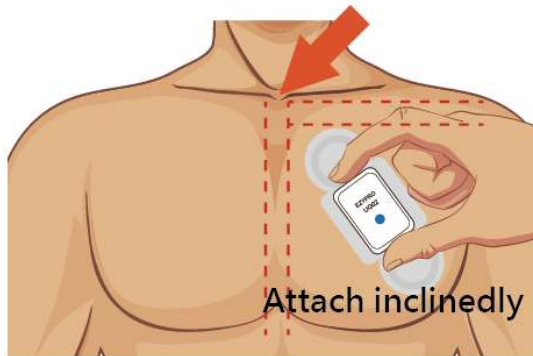


STEP 6 Apply

Hold the device as shown, inhale and straighten the chest slightly.

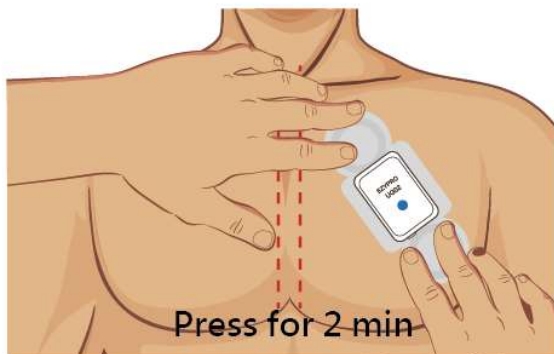
Attach the device central part first on the chest, then the surrounding area. (Device is attached inclinedly.)

Press the patch with fingers to make sure the it is tight to the skin.



STEP 7 Continuously press the whole patch against the chest

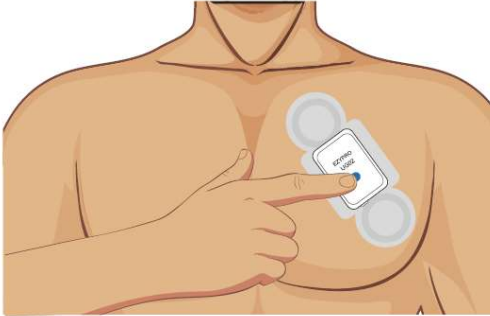
Press the entire surface area for 2 minutes to smooth out any wrinkles especially around the patch.



STEP8 Boot

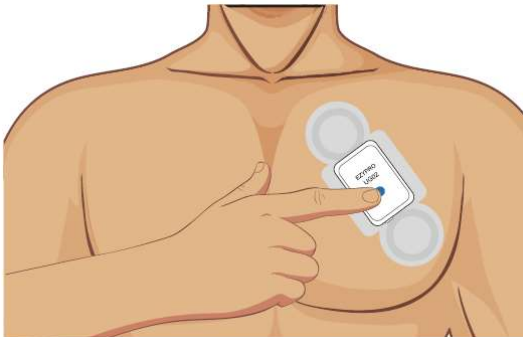
Press the blue button, the **green light** keeps showing for 30 seconds to indicate startup. Heartbeat rhythm will be recorded starting from this moment.

If the **orange light** instead flashes 5 times then turning off, it means the patch does not adhere completely. Press the patch especially electrodes area for 2 minutes and repeat startup. If electrodes contact well, it will activate the device successfully.



STEP9 Mark event

Press the blue button when the discomfort occurs and fill out a page of "Button Press Log". Device will label a mark in ECG records. This information will be helpful for further judging the patient's conditions.



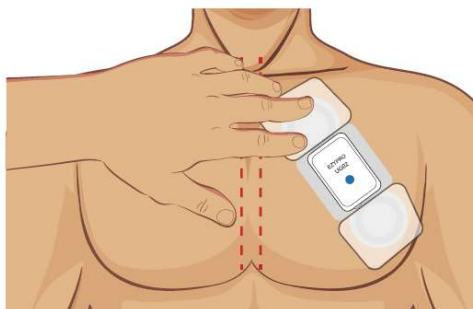
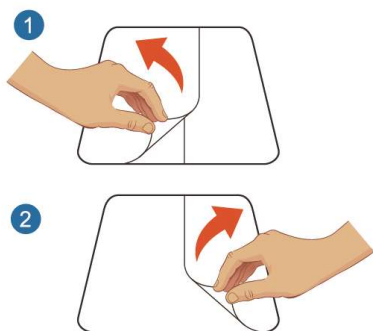
SIGKNOW

HOW TO USE OVERLAY TAPE?

Use the overlay tape when the patch becomes not sticky or already adhering over 7 days.

First, remove the one side white paper coverings of the tape, then horizontally attach on the electrode (this method is like using band-aid.)

Second, remove the other side covering and let the tape totally cover on electrodes.

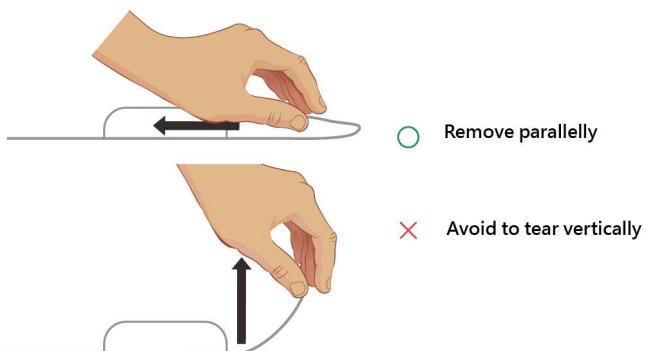


HOW TO REMOVE?

To avoid pain sensation and gel residues, remove the device parallelly to the skin surface as shown.

After removal, return the device and the log to the medical institutions.

Use wet cotton or alcohol pad to clean and remove the remaining gel on the skin.



HOW TO REVIEW LIVE ECG SIGNAL?

STEP1 Download APP “EZY iSee”

Access to “EZY iSee” download resource on SIGKNOW website and install it on a Bluetooth enabled device such as the tablet PC.

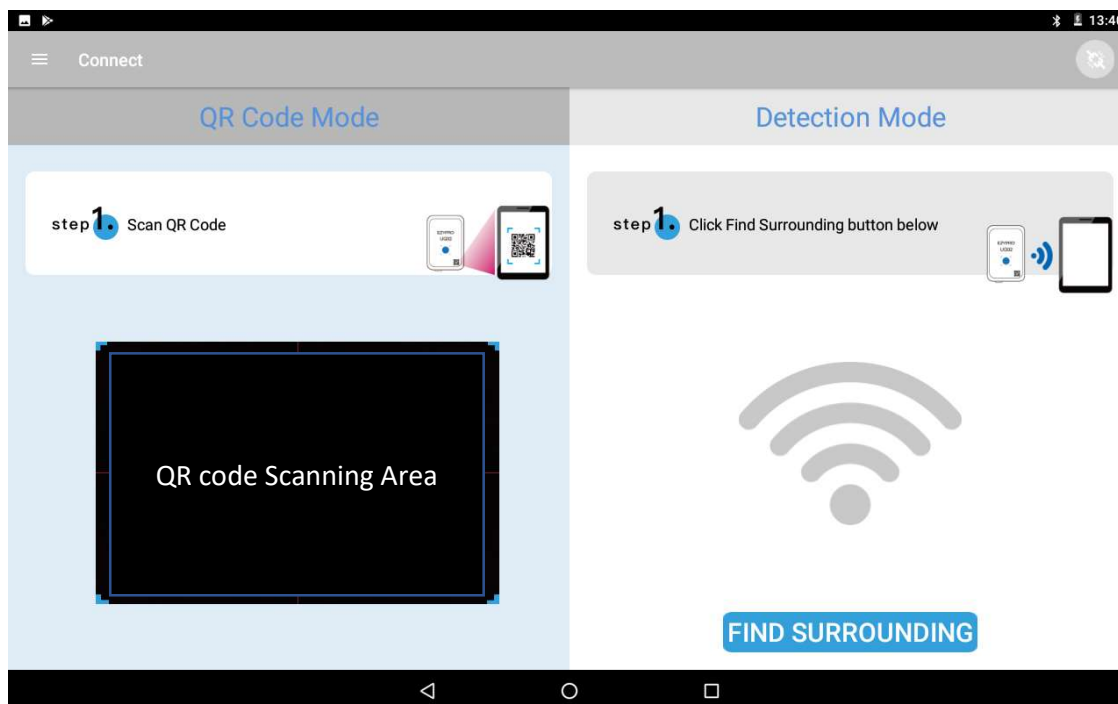
Basic requirement of the hardware:

- Android 4.3 or above
- CPU quad cores 1.3GHz
- 2GB RAM or above
- 2GB free space or above



STEP2 Connect to device

Click “EZY iSee” icon to active. Main screen as shown.



APP offers two methods to connect the device, choose one to operate.

➤ Module 1 “QR cord mode”

Follow the “EZY iSee” instruction, aim the tablet to the recorder QR cord and scan.

Press the blue button for 3 seconds to turn on Bluetooth, then the recorder will connect to “EZY iSee”.

During connecting, do no remove the recorder from the body.

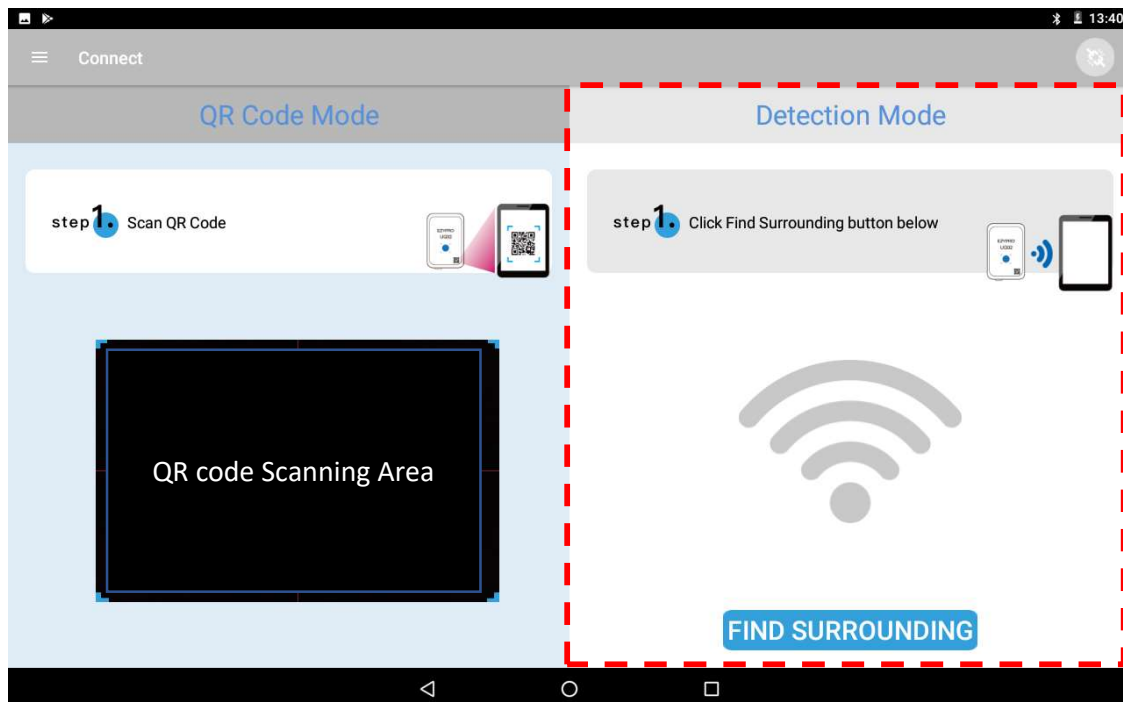


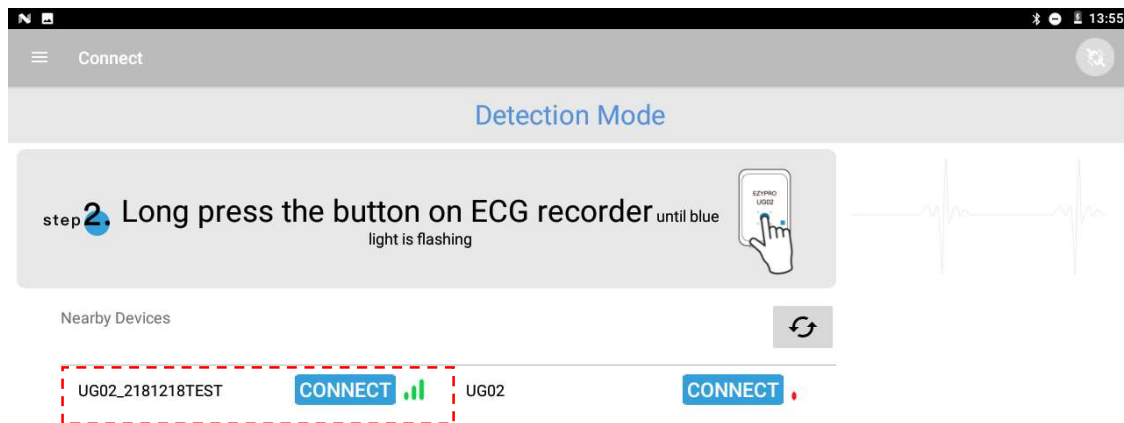
➤ Module 2 “Detection mode”

Click the “Find Surrounding” button on the main screen and press the recorder blue button for 3 seconds to turn on Bluetooth.

“EZY iSee” can detect the target recorder and shows device serial number. Device serial number can be found at side of the device. Check the number on screen and click “Connect” button to confirm.

During connecting, do no move the recorder from the body.

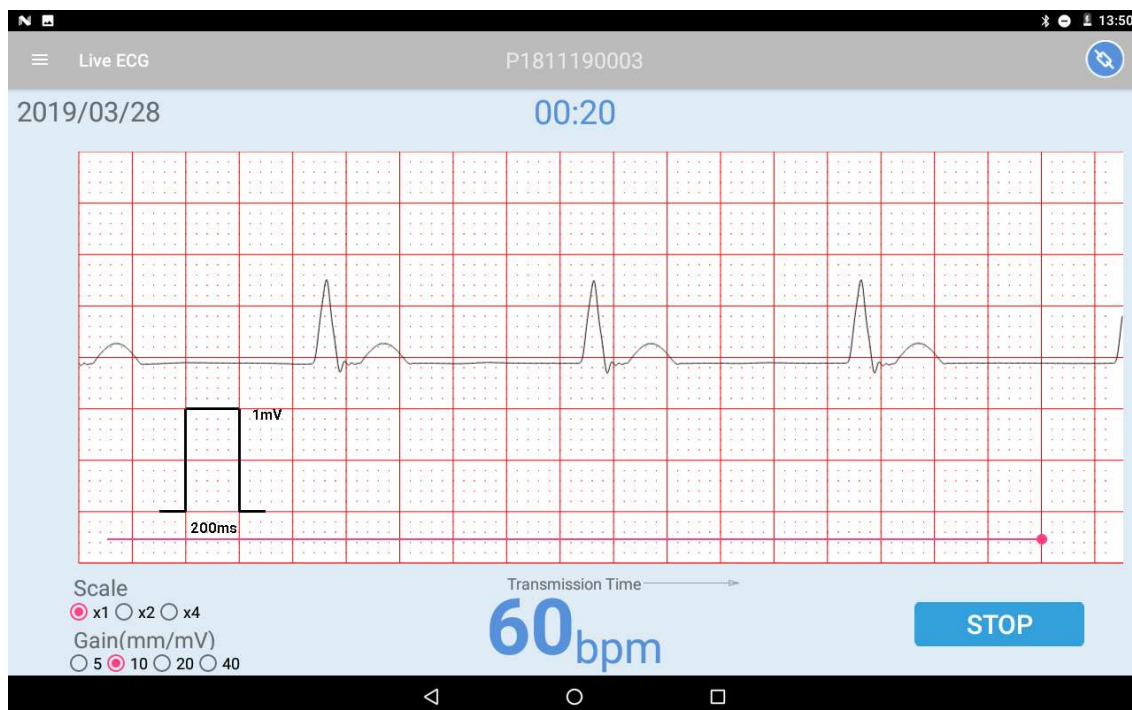




STEP3 REVIEW

When connection is successful, the recorder will automatically transmit live ECG signal to “EZY iSee”. Live signal screen as shown and is able to slide at will.

Total transmitting time is restricted to 30 minutes and the single transmission time will show on live signal screen.



EZYiSee general indicator

	Disconnect indicator: Recorder unconnected		Connect indicator: Recorder connected. Click to disconnect and turn off Bluetooth.
	Gray fixate indicator: Screen is unlocked and allow to slide wantonly.		Red fixate indicator: Screen is locked.
	Research indicator: Click it to research the surrounding recorder under Module 2 "Detection mode".		

STEP4 STOP TRANSMISSION/ DISCONNECT

At the end of review, click the "Stop" button on the screen to stop transferring.

Or click the "Connect indicator" icon to disconnect the recorder and turn off Bluetooth.

When the following situation happens, the recorder will automatically turn off Bluetooth and stop the blue light flashing.

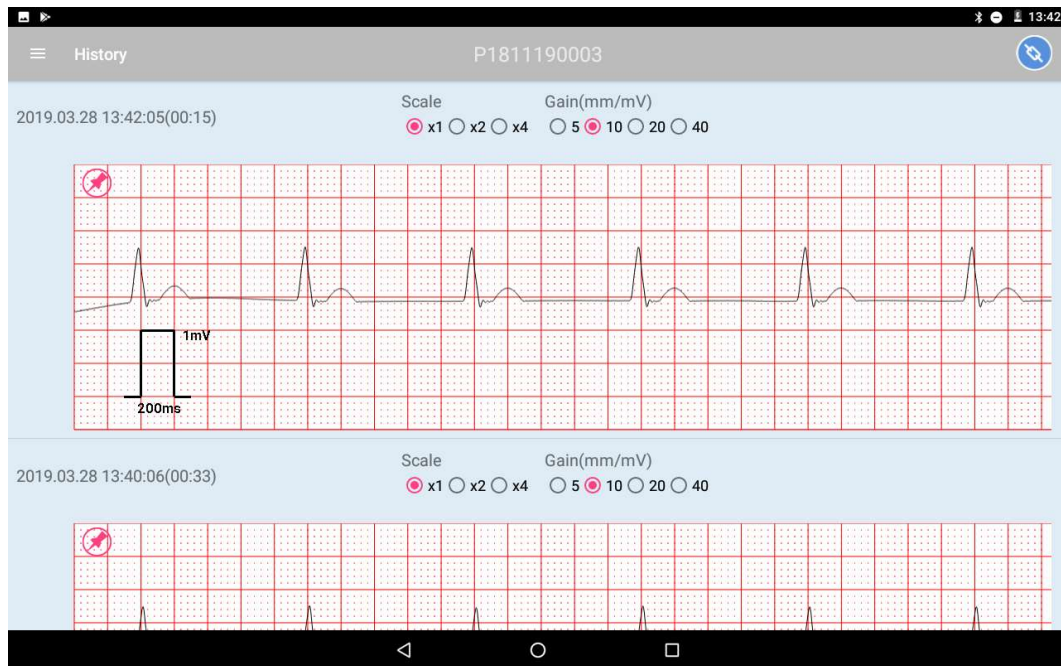
- Unsuccess to connect "EZY iSee" within 2 minutes.
- Connected, but over 3 minutes without any operation on the App.

If the transmitting time is over, the recorder will turn off Bluetooth and can't be connected.

STEP5 HISTORY SIGNAL

Click the “History” button to review multiple transferred ECG signals.

The screen can be slide and fixated by clicking the “Red fixate indicator” button.

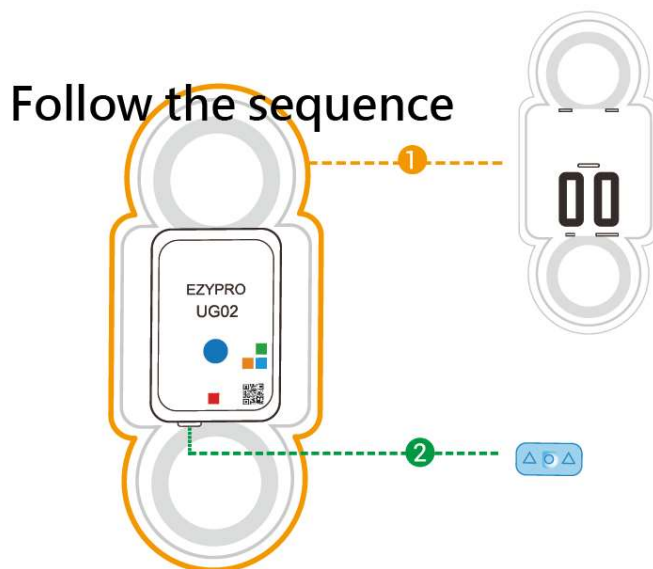


HOW TO DOWNLOAD/ ERASE DATA?

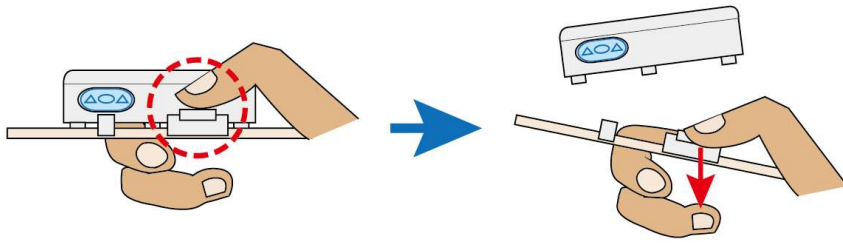
Remove the device from the chest first, please refer to the “HOW TO REMOVE” section.

STEP1 Remove accessories

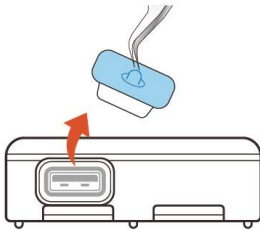
Please follow this sequence: (1) Patch and (2) Waterproof plug.



- (1) Push the patch bigger boarded latch down first. Then pull the device from the patch.
The removed patch shall be no longer used again, please discard it directly.



- (2) Use the tweezer to clamp the cylinder on the waterproof plug and move it out.



Waterproof plug are designed to reuse before it goes broken. Note to keep away from children and avoid them swallowing.

STEP2 Download/ Erase data

Connect the device to the PC, then active “UG02 setting tool” program.

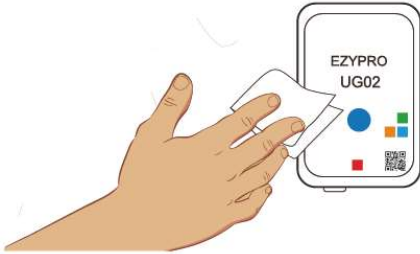
Click the “Download” button below the screen and save the file.

Note to confirm signal data have been archived before format. Once the device been formatted, the data will be erased and can’t be undo.

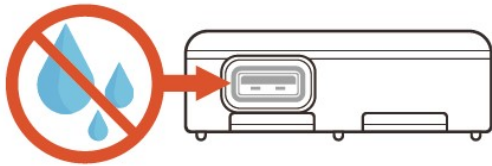
HOW TO MAINTAN?

STEP1 Clean

Use alcohol pad or wet cotton to swipe the recorder surface.



Note to keep the USB slot dry.



STEP2 Charge

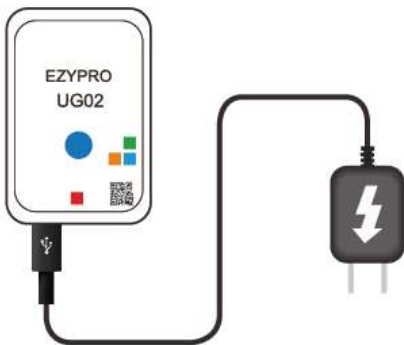
Check if the USB slot is wet or watery before charging.

Only use the adapter supplied with this product.

Do not charge the recorder while wearing, to avoid leakage or excessive the recorder temperature resulting in skin burns.

The green light will continuously flash until full battery or use "UG02 setting tool" program to check the battery status.

Note to not operate the recorder while charging.



STEP4 Storage

Store in the environmental required in the " Specifications" section.

To avoid the battery power is too low, result in the battery life damage, the recorder must be charged every 3 months in long-term storage.

Do not place any object of the recorder or strike it.

Q & A

Q 01. What is the EZYPRO doing?

A 01. The device can record and store every heartbeat for the physician as a diagnostic reference.

Q 02. How to boot?

A 02. After attaching the EZYPRO, press the blue button to boot. The green light keeps showing for 30 seconds to indicate startup. Heartbeat rhythm will be recorded starting from this moment. If the orange light instead flashes 5 times then turning off, it means the patch does not adhere completely. Press the patch especially electrodes area for 2 minutes and repeat startup. If electrodes contact well, it will activate the device successfully.

Q 03. The application site is slight redness, swollen or itching.

A 03. This product complies with regulatory requirements however everyone has a different sensitivity. Some users may experience itching due to temporary skin discomfort. To reduce the discomfort, try to keep in a dry and cool environment and avoid heavy sweating in exercise when wearing EZYPRO. If the itching and redness persists, please consult the medical institution for further consultation.

Q 04. How long should the patient wear this device?

A 04. Wear EZYPRO according to the physician prescribed wearing duration but not longer than 14 days. Based on individual wear experiences the actual wearing time may be shorter than prescribed.

Q 05. What should I do if the EZYPRO falls off?

A 05. Do not wear the recorder again, save it properly and return to the medical institution.

Q 06. What should I do if I feel unwell?

A 06. Press the button and fill out a page of Button Press Log. If the discomfort persists or worsens, seek medical attention immediately.

Q 07. What if I forget or miss to press the button?

A 07. That's okay. The EZYPRO still records every heartbeat continuously.

Q 08. What if I press the button but forget to write the event down on the Button Press Log?

A 08. That's okay. The EZYPRO still records every heartbeat continuously, and it also labeled the timing you pressed the button.

Q 09. Can I exercise while wearing the EZYPRO?

A 09. Yes, but heavy sweating may induce skin irritation and shorten the wearing duration.

Q 10. Can I shower while wearing the EZYPRO?

A 10. Yes, but showers should be brief and avoid taking a bath. Keep soaps away from the device. When towel-drying, hold the EZYPRO down with one hand.

Q 11. Can I go swimming while wearing the device?

A 11. No. The device should not be used underwater.

Q 12. Can I travel while wearing the device?

A 12. Yes. Show the security check statement in this manual while passing airport security gate for metal detector or other concerns.

Q 13. What if the patch moves slightly from its original position?

A 13. That's okay. The ECG signal may be smaller, but the recorder is still working normally.

Q 14. There is bleeding on the skin under the patch.

A 14. It is likely due to a small shaving cut. Do not apply this device on the wound.

Q 15. After removing EZYPRO, the orange light continuously flashes.

A 15. It is a normal phenomenon.

Q 16. What should I do if my skin sticks after removing EZYPRO?

A 16. Use wet cotton or alcohol pad to clean and remove remaining gel residues on the skin.

Q 17. What should I do after removing EZYPRO?

A 17. Bring the recorder together with the button press log back to the medical institution for analysis.

Specifications

01. Channels: 1, Single lead
02. Sampling rate: 256Hz
03. Resolution: 18bit
04. Input impedance: >10M Ω
05. Common-mode rejection ratio: >60dB
06. Heart beat: 30-250bpm (beats per minute)
07. Frequency response: 0.67Hz to 40Hz
08. Dynamic input range: ± 5 mV
09. Recording duration: Adjustable to 1~14 days.
10. Power supply: 360 mAh lithium polymer battery(typical)
11. Storage: MicroSD card
12. Power consumption: max. 400mW
13. Dimensions (without patch): 47(L)x32(W)x12(H)mm (+/-1mm)
14. Weight: 20g (+/-1g) (without accessories)
15. Ingress protection: IP24
16. Operating temperature: 5°C ~ 45°C (41°F - 113°F) (Max. surface temperature of the patch: 46°C while the ambient temperature is 45°C)
17. Operating humidity: 15% ~ 93% RH (non-condensing)
18. Operating atmospheric pressure: 700 ~1013hPa
19. Transportation/Short-term storage temperature: -20°C ~40°C(-4°F~104°F)
20. Long-term storage temperature: 5°C ~ 30°C (41°F ~ 86°F)
21. Transportation/storage humidity: 10% ~ 95% RH (non-condensing)
22. Transportation/storage atmospheric pressure: 700 ~1013hPa
23. Service life: Repeated charging about 500 times.

EMC Declaration

Manufacturer's declaration-electromagnetic emissions		
The <u>UG02</u> including AC-adapter is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the <u>UG02</u> including AC-adapter should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 2	The <u>UG02</u> including AC-adapter 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. The <u>UG02</u> including AC-adapter 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Manufacturer's declaration-electromagnetic immunity			
The <u>UG02</u> including AC-adapter is intended for use in the electromagnetic environment specified below. The customer or the user of the <u>UG02</u> including AC-adapter 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%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines input/output line: not applicable	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) 2kV line(s) to earth	±1kV line(s) to line(s) line(s) to earth: not applicable	Mains power quality should be that of a typical commercial and/or hospital environment.

Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T ; 0.5 cycle 0 % U_T ; 1 cycle 70 % U_T ; 25/30 cycles Voltage interruptions: 0 % U_T ; 250/300 cycle	Voltage dips: 0% U_T ; 0.5 cycle 0% U_T ; 1 cycle 70% U_T ; 25/30 cycles Voltage interruptions: 0% U_T ; 250/300cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the <u>UG02</u> including AC-adapter requires continued operation during power mains interruptions, it is recommended that the <u>UG02</u> including AC-adapter be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	The <u>UG02</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The <u>UG02</u> including AC-adapter is intended for use in the electromagnetic environment specified below.			
The customer or the user of the <u>UG02</u> including AC-adapter should assure that is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms: 150kHz – 80 MHz 6 Vrms: in ISM bands between 150kHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the <u>UG02</u> including AC-adapter including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \sqrt{P}$ 150kHz to 80MHz $d = 0.6\sqrt{P}$ 80MHz to 800MHz $d = 1.2\sqrt{P}$ 800MHz 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, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m	

			
NOTE1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UG02 including AC-adapter is used exceeds the applicable RF compliance level above, the UG02 including AC-adapter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UG02.		
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.		

Recommended separation distance between portable and mobile RF communications equipment and the <u>UG02 including AC-adapter</u>			
The <u>UG02</u> including AC-adapter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <u>UG02</u> including AC-adapter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <u>UG02</u> including AC-adapter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \sqrt{P}$	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2,7 GHz $d = 1.2\sqrt{P}$
0.01	0.1	0.06	0.12
0.1	0.32	0.19	0.38
1	1	0.6	0.12
10	3.2	1.9	3.9
100	10	6	12
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.			
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbol Explanation

	Caution
	Consult instructions for use
	Refer to instruction manual/ booklet
	Serial number
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
	Discarded ECG recorder shall be disposed in the container labeled with WEEE. Please dispose all wastes with appropriate protections according to local laws and regulations.
	Type BF equipment
	Keep away from sunlight
IP24	Ingress Protection / 2: Protected against a solid object greater than 12.5 mm such as a finger / 4: Protected against water splashed from all directions. Limited ingress permitted.
	Direct current
	Other resins

FCC Compliance 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.

FCC Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate the equipment.

This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Radiation Exposure Statement

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 radiofrequency (RF) energy set by the Federal Communications Commission of the U.S.

Government.



Sigknow Biomedical Co., Ltd.

6F., No.760, Sec. 4, Bade Rd., Songshan Dist., Taipei City 105,
Taiwan (R.O.C.)



MDSS GmbH

Schiffgraben 41, 30175 Hannover, Germany

Customer Service Hotline: +886-2-27612577

Customer Service Email: contact@sigknow.com.tw

71.UG202.0xx V1.001