EZYPRO ECG Monitoring System

Model：UG03

Released date: January 31, 2024

Please read this manual carefully before using the device.

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Product Introduction

EZYPRO ECG Monitoring System Model UG03 is an integrated electrocardiogram measurement system, consisting of the following components:

(1) Wearable ECG Recorder: capable of measuring single-lead or three-lead electrocardiogram (ECG) signals for a recording period of up to 14 days, depending on the patient's condition. It also offers the option to enable the detection of arrhythmia events and transmit them via Bluetooth.
(2) UG03 Setting Tool: a software program designed for Windows operating systems to configure Recorder parameters.
(3) Disposable electrode patches: adhered to the skin to collect ECG.
(4) EZY iLink: a mobile application that pairs with the Recorder, displaying ECG signals.
(5) EZY Care ECG management system: a cloud-based platform to receive, store, display and analyze the ECG transmitted from the App EZY iLink. The system builds in algorithm to analyze the received ECG and outputs result for manually check by the medical professionals. Medical professionals can inspect the ECG and edit the result through the user interface on the browser. Then the physician can make final medical judgement accordingly.

After wear, medical professionals also can download all ECG recording files using the UG03 Setting Tool for analysis with the EZYPRO Analyzer ECG analysis software (not included in this system).

This system does not provide real-time ECG transmission and is not suitable for monitoring or life-support applications. It does not offer automated arrhythmia diagnosis and cannot replace physician assessment or provide emergency notifications.

During wear, this system lacks emergency response and reporting capabilities. In case of emergencies, patients must contact medical or emergency services for assistance, as this system does not initiate notifications or contact healthcare institutions. The purpose of this product is to provide medical professionals with patient ECG information for analysis and decision-making.

Intended Use

EZYPRO ECG monitoring system Model UG03 is a prescription-only device and intended to capture cardiac events and continuously record electrocardiogram for long-term monitoring up to 14 days. The system can be configured to provide remote ECG monitoring capabilities and non-real-time interpretation according to user needs.

Intended medical indication

EZYPRO ECG Monitoring System Model UG03 is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of

breath, dizziness, light-headedness, presyncope, syncope, fatigue or anxiety.

Adverse Reactions

If patients experience redness, swelling, severe irritation, or allergic reaction (such as hives) during wear, remove ECG Recorder immediately.

⚠Contraindication & Warning

1. Do NOT use this product on allergies to the adhesive or hydrogel, or patients who have a family history of adhesive allergy.
2. Do NOT apply this product over an open wound.
3. This product is only intended for adults aged 18 and above and is not suitable for pregnant women and patients with hyperhidrosis.
4. ECG Recorder shall be removed before AED rescue. MRI, CT, and neurostimulation therapy are inadvisable during the use of this device.
5. This device should not be used adjacent to or stacked with other equipment.
6. Please do not use any other cables or accessories not approved in this manual to avoid negative influence on electromagnetic compatibility.
7. Use of accessories or products of other brands will void the product warranty and may cause damage to you, others and or the Pump concentrators cause injury.
8. Household electronic devices such as humidifiers, heaters or microwaves, and so on may be susceptible to cause interference with the device.
9. Any part of the monitor should be used no closer than 30 cm (12 inches) to wireless communication devices, such as networking devices, mobile phones, and walkie-talkies, or it can result in error display or inaccurate results.
10. Do NOT apply this product on infants whether or not their weighing is less than 10 kg.

⚠Important Information

1. This product should be used as directed by a physician, and the recording duration can be set in units of "minutes," "hours," or "days," up to a maximum of 14 days. Depending on skin type and daily activities, this product may fall off prematurely.
2. Do not use this product if you are allergic to adhesives or hydrogels, have a family history of adhesive allergies, or if the skin at the application site has wounds or inflammation.
3. Users with sensitive skin or other known conditions may experience side effects during use, such as skin redness, severe itching, or allergies. If these symptoms occur, discontinue use immediately and consult a medical professional.
4. If the product is removed prematurely, the recorded ECG data can still be used as reference

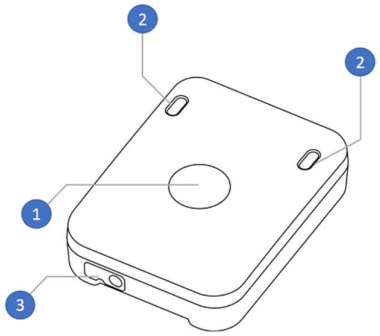
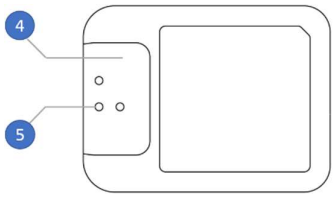
material for physician diagnosis.

5. When using this product in conjunction with the electrode patches, excessive sweating over a short period may lead to delayed evaporation of sweat, potentially resulting in skin itching and redness.
6. This product does not have an alarm function; it is solely for recording purposes. The ECG data is intended for reference by physicians during diagnosis and is not a diagnostic result.
7. This product is a precision measuring instrument; please avoid strong impacts or drops.
8. Do not place this product in a high-pressure sterilizer or gas sterilizer (e.g., EO, formaldehyde, high-concentration ozone, etc.).
9. Use of this product in strong electromagnetic environments may affect its measurement performance.
10. Do not use benzene, gasoline, or any other volatile detergent to clean this product or electrode contact points.
11. This product does not require regular calibration or component replacement. If repairs are needed, please contact our customer service, and do not disassemble the device by yourself.
12. It is recommended that a medical professional assist with the application of this product.

Product Contents

EZYPRO ECG Monitoring System (Model UG03)			
System Components		Model	Description
1. ECG Recorder		UG03-R	Capable of recording multi-lead ECG signals for up to 14 days. Working mode: Recorder mode, MCT mode
2. Disposable ECG Electrode Patches	Single-lead Patch	UG03-P1	Contains a pair of electrodes
	Three-lead Patch	UG03-P3S	Contains three electrodes
	Three-lead Patch	UG03-P3C	Contains three electrodes with 3 lead wires
3. Mobile Device Application		EZY iLink	Android APP
4. Recorder Configuration Tool		UG03 Setting Tool	Windows OS software
5. Cloud ECG Management System		EZY Care	Cloud-based Website
6. Recorder Power Adapter		N/A	Medical-grade power adapter Input：100 to 240V ~ 0.2A 60/50Hz Output：5V 1200mA 6W Max
7. Micro USB Cable		N/A	Cable length: 1 meter
8. Overlay Tape		N/A	Used to improve adhesion around the patch area, for one-time use.
9. Dust Plug		N/A	Protects the recorder's USB port from dust entering the device.

ECG Recorder Diagrams

Front View: (1) Start button/ Event trigger button (2) LED lights (green/orange/blue) (3) USB slot (Do not remove it during wear)	
Back View: (4) Cartridge groove (5) Conductive contacts (Do not touch pins during charging)	

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.)

- Heart rate calculation formula

$$\text{Heart Rate} = \frac{60}{\text{R} - \text{R Interval}}$$

- Pause determination

$$\text{RR Interval} \geqq 3 \text{ seconds}$$

Essential Performance

ECG recorder continuously records ECG and capture cardiac events after receipt of ECG. In the event the ECG recorder can't record in a timely manner, the ECG recorder alerts users that the functionality is impaired.

Product Features

1. Can continuously record ECG signals for up to 14 days, with recording time adjustable based on patient conditions.
2. Can store ECG signals, and recorded files are available for download and further analysis.
3. Optional built-in arrhythmia detection algorithm for detecting specific arrhythmia events.
4. One-button operation, patients can mark down any discomfort by pressing the button on the Recorder.
5. Only the Patch needs to be replaced, the Recorder can be recharged for multiple uses after charging.
6. Bluetooth transmission capability for checking of ECG signals on mobile devices using the EZY iLink app.
7. Suitable for showering and daily activities, without affecting appearance.

Usage Instructions

1 Follow the instructions in the "Product Specifications" section for the recommended operating environment. If you encounter any defects or malfunctions during normal use after opening the product, we will provide free replacement or repair. We are not responsible for any abnormalities or damage caused by not using or storing the product as specified in the original instructions.

2 Please wear the product according to the physician's instructions and hand it over to a medical professional during follow-up appointments. If ECG data analysis is required, please use our analysis software (not included with the product).

3 The product has temperature and humidity limitations. If patients are exposed to an unexpected environment, they may experience degradation of adhesive performance of the patch. It may cause the recorder falling off. Skin burns may occur if patients are exposed to high temperatures (ambient temperature >45°C). Staying in cool and comfortable environments is recommended.

4 The product includes ECG electrode patches.

- The Patch is a disposable product for single use; assemble it onto the Recorder immediately after opening.
- Please ensure the Patch is correctly positioned (refer to the "How to Wear EZYPRO" section). If removed and reapplied, it may affect measurement performance or become non-adhesive.
- Avoid touching the electrode on the back of the Patch with fingers during application to prevent static electricity from affecting the Recorder's performance.
- Do not allow Patch wires to touch other metal conductors.

5 Within the first 2 hours of wearing the product, avoid bathing or engaging in physical activity to prevent compromising adhesion.

6 During wear, patients can continue daily activities. Patients shall be gentle when putting on or taking off clothing to avoid interfere with the device. It is recommended to stay in a cool and comfortable environment, such as an air-conditioned room, to extend the wearing time.

7 Avoid vigorous or sweaty activities. Excessive sweating can cause the product to slide, reduce patch adhesion, affect signal quality, or cause the product to fall off, shortening the wearing duration.

8 The product body is waterproof, allowing for showering during wear, but activities such as baths, steam baths, swimming, and diving are prohibited.

- It is recommended to shorten the shower time, and use water with appropriate temperature. Prolonged showers or excessively hot water may cause the device to slide, generate noise, and affect the quality of ECG signal measurement.
- Avoid directly spraying water on the device and keep soap and shower gel away from it. When towel-drying, pat the area near the recorder. At the same time, press the Patch against your skin to secure it.
- If the Patch surface becomes wet, allow it to air dry naturally.

9 When patients experience mild physical discomfort, such as palpitations, shortness of breath, dizziness, fatigue, anxiety, rapid breathing, or any similar symptoms, he shall press the button on the device. The Recorder will automatically mark this event for reference by the attending physician. If the discomfort persists or worsens, patients shall seek immediate medical attention.

10 If the Patch edges start lifting, press the Patch wings evenly for 2 minutes to smooth out any wrinkles or air bubbles. If the edges are barely sticky or the Patch has been worn for more than seven days, use the Overlay Tape to enhance the adhesion.

11 Please use the dedicated power adapter provided to charge this product. (Charging should only be done by medical professionals.)

- Before charging, please check the USB port for any moisture or water accumulation. Wait for the moisture to evaporate before proceeding to avoid short-circuiting the device.
- The battery can be recharged approximately 300 times. To minimize battery degradation, it is recommended to charge it at least once every three months during storage. Before wearing, check the battery level to ensure the device operates with sufficient power.

12 Choking hazard: The Recorder contains small accessories that may be dangerous if swallowed. Keep them out of reach of children.

13 EZY iLink is used to check the signal quality while wearing the Recorder.

- During the Bluetooth pairing, transmission, and checking of ECG signals, please keep wearing the device; do not remove it prematurely.
- Maintain a distance of no more than 1 meter between this product and the mobile device. Avoid simultaneously using Bluetooth headsets, Bluetooth wristbands, or other electronic devices with Bluetooth functionality. Also, steer clear of microwave ovens, motors, Wi-Fi signal sources, and other potential sources of signal interference.

14 Please install the company's configuration software, "UG03 Setting Tool," on a personal computer. UG03 Setting Tool is used for configuring the Recorder, including recording duration and other basic parameters. It is intended for use by healthcare facilities only.

15 In case of urgent physical discomfort, the user must contact emergency medical services (such as 119) or visit a medical facility for assistance. This product is subject to various factors affecting wireless communication systems and is not an immediate monitoring system. It will not contact the user in the event of an emergency, nor can it substitute for the user's request for emergency assistance.

16 In the “MCT Mode”, the ECG recorder will regularly transmit the obtained ECG signals to EZY iLink, and EZY iLink will further forward it to EZY Care Management system. The total number of manually triggered uncomfortable events (press the green button) and the number of arrhythmia events automatically detected by the recorder is up to 700 times. If the limit is reached, the event transmission will be stopped, but the recorder will still regularly transmit the recorded ECG signal to EZY iLink.

Intended User

Intended user / Applying Steps	Medical professionals	Patients
Use UG03 Setting Tool	X	
Assemble Accessories	X	
Use EZY iLInk	X	X Edit the Event logs.
Wear EZYPRO	X	X Mark the Discomfort Event
Use Overlay Tape	X	X
Remove	X	
EZY iLink Service	X	
EZY Care Service	X	
Maintenance	X	

LED Light Guide

The light indication is only related to the status of Recorder. The lighting does **NOT** represent patient's health condition.

Situation	**Lights Position on Recorder**	**Description**	**Lights**
Power On	Right side	The device starts recording. No light flashes during recording.	Green Light on for 30 seconds.
Power On	Right side	Patch makes poor skin contact (lead off). Press the entire Patch and the wings firmly for 2 minutes. Restart the Recorder.	Orange Light flashes 5 times.

Applying Instructions

How to Use UG03 Setting Tool

Step 1 Install Software

Install the software “UG03 Setting Tool” on your computer.

PC requirements:

- Window 10, 64bit
- Hardware: CPU Intel i5, RAM 2GB
- Peripheral: PC with USB Type B port, screen, keyboard, and mouse.

Step 2 Recorder Setting

Use the qualified USB cable to connect the ECG recorder to your PC (refer to the “How to Assemble Accessories” section).

Execute UG03 Setting Tool and start setting.

UG03 Setting Tool Interface

	Function	Description
1	Device Status	“Not connected” is shown when the tool runs without connecting to the Recorder. “Connected” is shown when the Recorder is connected.
2	Device S/N	The serial number will autofill when the Recorder is connected.
3	Local Time	Once connected, your local time will show automatically. Local Time Format: yyyy/mm/dd hh:mm:ss (24hr)
4	Recording Duration	The duration will show once the Service S/N is set.
5	Service S/N	The serial number will show once the Service S/N is set.
6	Battery Voltage	The current voltage of the Recorder is displayed when it is connected. Note: Voltage must be > 4.20V
7	Working Mode	The working mode will show once the Service S/N is set.
8	Auto Arrhythmia Detection	The auto detection status will show if it is enabled or not once the Service S/N is set. During wear, the recorder will use its built-in algorithm to detect four types of arrhythmia events: Afib, Bradycardia, Tachycardia, and Pause.
9	Channel	One Channel or Three Channel options for the signal recording. This must be used in conjunction with the corresponding electrode patches. The number of channels will show once the Service S/N is set.
10	Initialize Device	To clear ECG data in the recorder. At your first use, the recorder is empty and ready for recording.
11	Begin Format	To clear the ECG data in the recorder, you must format the recorder. It CANNOT BE REVERSED once you begin. Make sure the previous recording is saved on your PC before formatting.
12	Set Service S/N	Follow the instruction to set the recorder and apply. Once the Service S/N is applied, the general information will autofill in “Device Status”.
13	Download Data	Download raw ECG data. You must download and save the data before reuse.
14	Convert file	Convert the stored ECG data into the MIT-BIH or HL7 format.

At your first device setting, please follow the steps:

(1) Set Service S/N: Please follow the instructions shown on the screen, enter the Service S/N, then “Apply”.

(2) Device Status: the system will automatically fill in general information. Please check if the content is correct.

Exit: Once you confirm the detail, exit the software. You can assemble the Recorder and Patch and attach to your patient.

Before reuse for your next patient, please follow the steps:

(1) Download Data: “Select” the designated folder to save the ECG raw data, and “Download”.

(2) Confirm: Once the data is successfully converted, the information box will pop up, please select “Confirm” to continue.

(3) Initialize Device: Execute “Begin Format” to clear the EC data saved in the Recorder. A waning will show to remind the user to confirm again if the ECG data is well preserved. **The process cannot be reversed. Please ensure the recorded data is saved in your computer before formatting**. Click on “OK” and start initializing the device.

(4) Exit: The Recorder is cleared and ready for the next use.

Note: Once formatted, the Bluetooth pairing between the ECG recorder and the mobile device will also be erased. The next time you use the recorder, please re-establish the pairing within the EZY iLink App.

How to Use EZY iLink

Step 1 access EZY iLink

We will provide Android smartphones with EZY iLink pre-installed and set to Kiosk mode. Please use the smartphone to perform the following steps.

Step 2 Set the Pairing Password

Enter the app and follow the instructions shown on the screen.

Set the ECG recorder's "Pairing Password" first.

Step 3 Connect with ECG Recorder

Press the ECG recorder button. Once the smartphone detects the Recorder, the Service S/N will show on the EZY iLink. Please click "Pair".

Step 4 Confirm Pairing

Tap the "Test" button on the screen. If the pairing is successful, the green light of the ECG recorder will flash.

Start EZY iLink Service

Step 1 Start Data Transfer

When completing the wear steps, enter the EZY iLink again and tap the "Start" button on the screen.

Step 2 Live View ECG

Tap the "LIVE ECG" button on the screen, the ECG signal starts running on the screen. Medical professionals can view ECG waveforms at different scale and gain.

The ECG data transmitted to the app is stored in the ECG Recorder as well. It does not affect the total monitoring time.

Step 3 User Event

Tap the "User Event" button, the User Event logs will show on the screen. Click the event to edit the Event logs.

How to Assemble Accessories

Step 1 Assemble Dust Plug

Tuck the dust plug into the USB slot of the recorder. The arrows on the plug should point upwards.

Do not remove the dust plug during wear.

Step 2 Assemble Recorder and Patch

(1) Hold the Recorder diagonally, align and fix the front-end slots of the Recorder into the Patch plugs.

(2) Press down the Recorder. You will hear snap sound when two parts are properly fixed together.

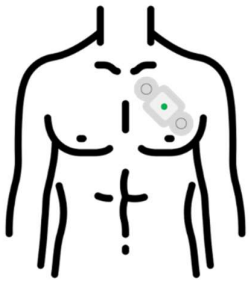
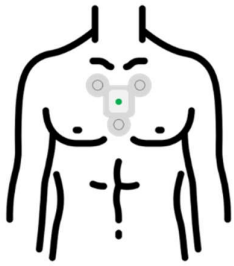
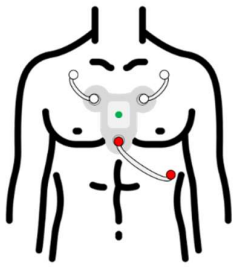
There shall be no space between the recorder and the patch.

3-lead Patch includes three wires, please ensure they are well assembled on the patch.

How to Wear EZYPRO

Step 1 Confirm Wear Area

The Recorder shall be attached on patient's chest. **Arrows on Patch should point upwards.**

Wear area		
Single-lead Patch (UG03-P1)	Three-lead Patch (UG03-P3S)	Three-lead Patch with wires (UG03-P3C)
Left chest, and one finger below the collarbone. 	Middle chest, and one finger below the collarbone. 	● Left chest (LA point), right chest (RA point), and one finger below the collarbone. ● Below the ribs on the left abdomen (LL point). 

Step 2 Shave

Use a razor and gently shave hair in the area. Skip if no hair present.

Step 3 Clean

Use a wet cotton pad or an alcohol pad to clean the area. Let dry for 2 minutes.

Step 4 Remove Paper Backings

Remove the paper backings of Patch one at a time. **Do NOT touch the adhesive once the backing is removed.**

Step 5 Attach Recorder

Hold the recorder diagonally and place it on the wear area. **Make sure the arrows are pointing upwards.**

Step 6 Press for Good Skin Contact

Press firmly and evenly the entire Patch for 2 minutes to make sure good skin contact. Try to smooth out any wrinkles or air bubbles. A good skin contact will help increase the monitoring accuracy.

Step 7 Start Recorder

Press the green button to start the Recorder. Green Light will turn on for 30 seconds to indicate a successful power on. Recorder starts recording. During normal recording, there is no light on. If you encounter abnormal lighting, please see "**LED Light Guide**" for trouble shooting.

The functions supported by the two working modes of the ECG recorder include software operation as follows:

Functions / Mode	ECG Recording	Button trigger events	Automatic detection arrhythmia events*	EZY iLink ECG Display	EZY iLink Event editing	EZY Care Cloud Management
Recorder Mode	X	X		X		
MCT Mode	X	X	X	X	X	X

*Automatic detection arrhythmia events include Atrial Fibrillation, Tachycardia, Bradycardia, and Pause.

Step 8 Discomfort Event Marking

Patient can mark any discomfort by pushing the green button. Green Light flashes 3 times to indicate a successful marking. The recorder will accurately save the event time for future analysis. This information will help physicians make diagnosis.

How to Use Overlay Tape

If you see edges starting to flip off or the prescribed wear time is more than 7 days, it is highly recommended to use Overlay Tape to strengthen the adhesion.

Remove the paper backings one at a time and stick them over the patch wings.

How to Remove

Step 1 Remove From Body

After wearing, remove the Recorder from the patient. To reduce pain and gel residues, tear off the Patch parallel to the skin. It is advised to use a wet cotton pad or alcohol pad to clean the attached area and gently remove any remaining gel.

Step 2 Separate Recorder and Patch

Hold the Recorder in the center, push down the hook and pull off the ECG Patch. **The Patch is for single use only**. Patch reuse is forbidden. Please follow the local laws for disposing of the medical waste.

Step 3 Remove Dust Plug

When you intend to charge the Recorder or reset it with UG03 Setting Tool, you have to remove the dust plug to use the USB slot. You can use a tweezer to remove the plug. **Keep the Dust Plug out of children's reach.**

EZY Care Main Function

- Account & Device Management
  - User registeration and password protection
  - Show or hide menus and action according to the user access rights.
- Patient ECG Management & ECG Comment
  - Provide management capability like grouping, ordering, and filtering, and searching to assist users to organize patients.
- ECG Review
  - Provide an interface for authorized user to view / modify / delete ECG strips.
  - Export PDF reports.

Environment Requirements

- Browser: Chrome 79 or later
- OS: Windows 10 or above, 64 bits. MacOS 14.0 or above
- Hardware: CPU Intel i5, RAM 4GB
- Peripheral: Screen (Solution 1920*1080 or above), keyboard, and mouse
- Network bandwidth: 100Mb or more, expandable according to needs

Maintenance

The ECG recorder is reusable and requires constant maintenance. Before maintenance, please ensure that the gathered ECG data has been downloaded and saved. **The Recorder should be formatted before next wear.**

Please make sure the Recorder is intact and clean for the next patient. Damages, such as cracks, dents, fractures etc., might affect recording performance. Please contact your local dealer for customer support.

Note: Calibration or component replacement is not required for maintenance. Check Accessory is available.

Clean

Please use alcohol pads or wet cotton pads to clean the Recorder. Avoid getting water or liquid into the USB slot.

Note: Do not clean the Recorder during wear. Please remove the device from the patient and separate it from the Patch before cleaning.

Battery Recharge

Before charging, please make sure the USB port is dry and no foreign objects. During charging, Green Light flashes continuously and stays on when the battery is fully charged. Please charge in a place that is convenient for plugging and unplugging.

For long-term storage, it is recommended to charge the Recorder every 3 months to avoid battery damage.

Note: Do NOT charge the device during wear. Do NOT operate the device during charging.

Storage

Store the Recorder under the condition specified in “**Specifications**".

Specifications

1. Channels: 1 or 3 (channels)
2. Dat Sampling rate: 256Hz
3. ADC Resolution: 18bits
4. Input impedance: >10MΩ
5. Common-mode rejection ratio: >60dB
6. Heartbeat: 30-250bpm (beats per minute)
7. Frequency response: 0.05Hz to 40Hz
8. Dynamic input range: ±5mV
9. Power supply: 520 mAh 3.8V lithium polymer battery
10. Rating: DC 3.8V, 520mAh (Lithium battery)/DC 5V, 0.5A (DC power port)
11. Three-axis accelerometer: +/- 2G
12. Wireless communication protocol: BLE 5.0, Band 2.402 GHz to 2.480 GHz
13. Dimensions: Recorder: 47(L)x35.5(W)x13.7(H)mm (±1mm)
14. Weight: Recorder: 20g (±1g)
15. 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)
16. Operating humidity:10% ~ 95% RH (non-condensing)
17. Operating atmospheric pressure: 700 ~ 10160Pa
18. Transportation/Short-term storage temperature: -20°C ~ 40°C(-4°F ~ 104°F)
19. Long-term storage temperature: 5°C ~ 30°C (41°F ~ 86°F)
20. Transportation/storage humidity: 10% ~ 95% RH (non-condensing)
21. Transportation/storage atmospheric pressure: 700 ~1060hPa
22. Arrythmia detection: AFib, Tachycardia, Bradycardia, Pause
23. IP Classification: IP26
24. Expected service life: 3 years of typical uses. Repeated charging about 300 times.
25. Shelf life: 12 months for electrodes patch.

Wireless Information

Wireless Specification	
Wireless Standards (Profiles)	GATT
Operation Modes	Peripheral
RF Output Power	Max transmit power of 0 dBm Receiver sensitivity of -90 dBm.
Power Consumption	Typical 10 mA @ 3.0 VDC
Bluetooth Version Support	Bluetooth Low Energy (BLE) 5.0 single-mode
ISM band	2.402 GHz to 2.480 GHz operation
Modulation Type	GFSK for BLE 1 Mbps

Symbol Glossary

	Caution
	Consult instructions for use
	Refer to instruction manual/ booklet
	Serial number
	Lot number
	Date of manufacture
	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
IP26	Ingress Protection / 2: Protected against a solid object greater than 12.5 mm such as a finger / 6: Protected from high pressure water jets from any direction. Limited ingress permitted.
	Direct current
	Other resins

EMC Declaration

Manufacturer's declaration-electromagnetic emissions		
The UG03 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the UG03 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	The UG03 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	The UG03 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity			
The UG03 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the UG03 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	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	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical

IEC 61000-4-4	± 1 kV for input/output lines	Not applicable	home healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s) ± 0.5 kV, ±1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ±1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare 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 cycles Voltage interruptions: 0 % *U*T; 250 cycles	Mains power quality should be that of a typical home healthcare environment. If the user of the UG03 requires continued operation during power mains interruptions, it is recommended that the UG03 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	The UG03 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The UG03 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the UG03 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms:	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms:	**Portable and mobile RF communications equipment should be used no closer to any part of the** UG03 including

Radiated RF IEC 61000-4-3	in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 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 metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			

Recommended separation distance between portable and mobile RF communications equipment and the UG03

The UG03 is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the UG03 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UG03 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 $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The UG03 is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of the UG03 should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home healthcare)
385	380 – 390	TETRA 400	Pulse modulation b)	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b)	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800,	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n,	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation b)	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The UG03 is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of the UG03 should assure that it is used in such an environment.

Frequencies	**Test Level [A/m]**	**Modulation**	**Dwell time [s]**	**Compliance LEVEL [A/m] (for home healthcare)**
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.

Statement

低功率射頻器材技術規範 LP0002

章節 3.8.2

取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

低功率射頻器材之使用不得影響飛航安全及干擾合法通信;經發現有干擾現象時,應立即停用,並改善至無干擾時方得繼續使用。

前述合法通信，指依電信管理法規定作業之無線電通信。

低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

Federal Communication Commission Interference 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.

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Radiation Exposure Statement: This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

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