



ECG Event Recorder

User Manual

Model: ECG-ME

This user manual describes the setup and use of the **ecgme** ECG Event Recorder. Before using **ecgme** you must carefully read this manual in its entirety, including warnings, contraindications and precautions.

Product information

Product Name : ECG Event Recorder

Model : ECG-ME

(EC) CERTIFICATE(S): G1 078995 0012 Rev. 01

ARTG Identifier: 371024

Sponsor

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Manufacturer

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User Manual

Version : 1.2

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1. Introduction

1.1 Purpose of this manual

The purpose of this manual is to provide general information and instructions for setup, operation, cleaning and maintenance of the **ecgme ECG Event Recorder**, and solutions to common problems.

1.2 Audience

This manual is intended for people who use the **ecgme ECG Event Recorder**.

1.3 Intended use

The ECG Event Recorder is for use by individuals and healthcare professionals in multiple settings including clinical, home and sporting environments. It is used in conjunction with software installed in an associated mobile device (smart phone) and is suitable for real-time single lead ECG signal acquisition, processing, wireless transmission and display.

Note: The intended use is to provide an ECG reference and analysis to support medical diagnosis. Its use does not replace the clinician in making diagnostic conclusions.

1.4 Equipment Supplied

- ECG Event Recorder
- Protective carry bag
- USB charging cable
- User manual

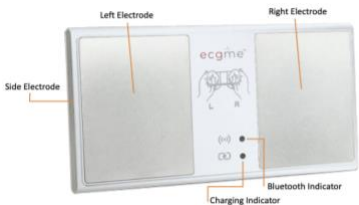


Fig 1 Front view of ECG event recorder

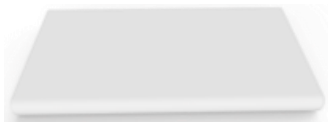


Fig 2 Back view of ECG event recorder

1.5 Technical Specification

Frequency Response	0.5Hz to 40 Hz
Input Impedance	≥ 3.0 MOhm
Input Range	0.05~6 mV
Sampling Rate	200 Hz
Resolution	12 bit
Size	87 x 49 x 7mm
Weight	33g
Battery	DC 3.7V Li-Ion
Warranty	12 months
Service life	5 years
Production date	See label on device

1.6 Warnings

Please be sure to read this manual before getting started. Incorrect operation may result in the loss of ECG data.

- If the **ecgme** App indicates that the battery is low, charge it prior to use.
- The device is charged by USB using supplied cable requiring a charging voltage of DC 5V, (use a charger certified by GB 9706.1 or IEC 60601-1).
- Do not use the device while charging.
- To ensure the accuracy of the ECG recording, the user should keep away from large electrical devices or other electromagnetic interference e.g. electric blankets and heating pads.
- Storage Conditions:
 - Temperature range: $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$
 - Humidity range: $\leq 80\%$
- Operating Conditions:
 - Temperature range: $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$
 - Humidity range: $\leq 80\%$
 - Atmospheric pressure range: $80\text{KPa} \sim 106\text{KPa}$
- The data generated by **ecgme** must be analysed by the Biosignals Diagnostics analysis platform through the mobile app.
- There are no user-replaceable parts of the **ecgme** device. Do not disassemble the device.
- The platform availability and detailed configuration requirements of the mobile phone App used with **ecgme** can be found

at the website link in Section 2.1 (page 9) of this manual.



You should consult your physician before using ecgme if you have :

- Coronary artery disease
- Heart valve disease
- Heart transplantation
- Heart failure

1.7 Operating environment

- This device cannot be used simultaneously with flammable anaesthetic gases mixed with air or O₂ or N₂O.
- This Device is IPX0 (not protected against fluid ingress).
- This device is internally powered, BF type device.
- The operation mode of the device is continuous operation.

1.8 Electromagnetic compatibility

- **ecgme** complies with the relevant requirements of YY0505 standard for electromagnetic compatibility;
- Users should install the required software and use the device according to the EMC information provided in the accompanying documentation;
- Guidelines and manufacturer's statements are detailed in the appendix.

WARNING: 

- **ecgme** should not be used in close proximity to or stacked with other equipment. If the device must be used in the above situation, it should be observed and verified that it works correctly in current configuration.
- The use of cables other than supplied by the manufacturer may result in increased emissions or reduced noise immunity of **ecgme**. Maximum length of charging cable is 0.8m.
- Minimum value of input signal:
 - Amplitude: 0.3mv
 - Frequency: 0.5HZ
 - Value lower than above standard may lead to inaccurate results.

1.9 Contraindications

- Patients with Parkinson's disease
- Patients with uncontrolled movement disorders

2. Mobile application

2.1 Download Mobile App

The mobile phone application (App) used in conjunction with **ecgme** is part of the monitoring system. Users can check availability and download the App for their smart phone platform by scanning the QR code below and following links on the website.



www.biosigdx.com/ecgme

2.2 Bluetooth

- 1) Enter the application;
- 2) Register and Login;
- 3) Select one of the tests and allow the App to access Bluetooth;
- 4) Hold the two electrodes of **ecgme** with both hands or put the device against chest as the guidance shown in the App. The App should automatically connect to the device.

If you wish to connect another **ecgme** device click 'Account' -> 'Available Device', then hold the two electrodes of the new device with both hands. Select the new device from the Nearby Device list to complete the device connection.

Note: When one ecgme device has connected with the mobile app, another ecgme device cannot concurrently send ECG data to the same mobile phone.

2.3 Login

a) Registration

Free registration can be completed with user's email address

b) Logging in

After registration, the user can login to the App with username and password

c) Guest Account

If a user doesn't wish to register, the user can use the guest account. The guest account will access the ECG tests without an automatic analysis report being generated.

2.4 Detection

Select a test item from 'Tests'. For example, Arrhythmia Check;

- 1) Click 'Arrhythmia Check', hold the **ecgme** device electrodes with both hands as shown in the guidance on the App test page;
- 2) After a short 2-3 second delay, the ECG waveform will be displayed on the screen;
- 3) Wait for the test to complete, select the symptoms and add more details if needed;
- 4) After submitting the data, an automatic analysis report will be sent back in 1-2 minutes.

2.5 ECG data

ECG data is the test record stored on the smart phone. When clearing the phone cache, the ECG data will be deleted.

On the Report page, a list of recordings is shown. Pulling down the list, the page will be refreshed. If the automatic analysis report has been completed, the icon of the recording will change from grey to coloured.

- Grey icon indicates the data has not uploaded yet and the test result is pending;
- Green icon indicates normal;
- Yellow icon indicates that there might be interference during test and it is recommended to retest;
- Red icon indicates that there may be an abnormal event and it is recommended to retest. If the user repeats the test 3 or more times by following the test instruction but the results still show abnormalities, assessment by a clinician is recommended.

Users can view the ECG data of the specific recording via the Report page.

- 1) Click Report on the bottom menu;
- 2) Select one recording from the list;
- 3) Click 'ECG data';
- 4) Zoom in and out of the waveform to view details;
- 5) User can share the data with others or clinician by clicking the upper right corner button.

2.6 Automatic analysis

Automatic analysis is an analysis report that is automatically generated by the analysis algorithm in the Biosignals cloud server. The analysis report can only be generated when ECG data are successfully uploaded to the server and will be stored in server. When clearing the phone cache, the report will be cleared, but when pulling down the recording list on the Report page in the 'Cloud' tab, the automatic analysis report will be downloaded from the server again. Users can view the automatic analysis of the specific recording via Report page.

- 1) Click Report on the bottom menu;
- 2) Select one recording from list;
- 3) Click 'Automatic Analysis';
- 4) Review the summary of the test and click 'Detailed Report' to view analysis report;
- 5) Zoom in and out of the waveform to view details;
- 6) User can share the data with others by clicking the upper right corner button.

2.7 Settings

2.7.1 User setting

Click 'Account' to enter the setting page.

2.7.2 Recording time

Click 'Account' > 'Settings' > 'Test Duration' to set the recording time.

2.7.3 Device selecting

When there is more than one device, user can link the new device via 'Available Device'. Click 'Account' > 'Available Device', hold the electrodes with both hands, then the name and ID of the

current device will appear under Nearby Device, click the name to connect.

2.7.4 Change password

Click 'Account' > 'Settings' > 'Update Password' to change the password.

2.7.5 Account switching

- 1) Click the user icon on the upper left corner of the home page;
- 2) Logout of the current account;
- 3) Login with other account details.

3. Operation Guide

3.1 Preparation

- 1) Ensure that the **ecgme** device is charged. When the device is charging, the "charging" indicator shows green.
- 2) For best results, wipe the skin that will be in contact with the electrodes with alcohol wipes or moist cloth.
- 3) Sit down, relax, and make firm contact between the electrodes and fingers (as in Fig 3) or chest (as in the guidance on the App test page). Remain still. The selected recording time can be 30 seconds to 10 min.

Note: For ecgme Non-stop mode see section 3.3

3.2 Device operation

- 1) Run the mobile App and select a test from the home page Tests area, place fingers on the electrodes of **ecgme**. The device will automatically start acquiring ECG data. The Bluetooth indicator on **ecgme** will flash blue and the ECG waveform will be displayed on the mobile phone **ecgme** App within 1 to 2 seconds.
- 2) When the fingers are not in contact with the device, the device will automatically power off in approximately 3 seconds.



Fig 3 Handheld mode

3.3 Non-stop ECG mode

Using the optional on-body adaptor kit, **ecgme** can be converted to a wearable device placed on the chest for 24 hours of continuous ECG monitoring. Detailed instructions about the on-body adaptor kit and its use are located online using the QR code in section 2.1.

3.3.1 Non-stop mode preparation

- 1) Prepare the chest skin by shaving if required and using alcohol wipes or moist cloth to ensure skin is clean and free from residue.
- 2) Install **ecgme** into the on-body adaptor with the electrodes face down. The “Side Electrode” should be closest to the larger blue tag. Connect the disposable ECG electrodes (supplied with the kit) to the adaptor by following the online instructions guide or the guide in App (from QR code in section 2.1).

3.3.2 Non-stop mode operation

- 1) Remove protective covers from the disposable ECG electrodes. Place the adhesive side firmly on the skin of the upper chest, securing on-body adaptor with the larger blue tab to your left as shown in Fig 4.

-
- 2) Run the mobile App and select 'ecgme Non-stop' as the test.
 - 3) The ECG data will be sent to the mobile phone and displayed on the App screen.
 - 4) **ecgme** will continue to record ECG data for 24 hours while on the body.
 - 5) At the completion of the 24 hour period the on-body adaptor can be removed by detaching the ECG electrodes.
 - 6) The automatic analysis will be sent back to the App and can be viewed on 'Report' page.

Note:

- **During the monitoring process, the App must remain running (foreground or background) and the phone must stay within the Bluetooth range;**
- **When test is complete, please stay in the App and keep the screen on while data uploads to the analysis servers;**
- **It may take up to 30 minutes for the automatic analysis report to be sent back.**

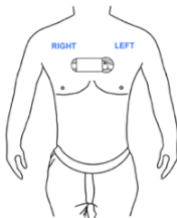


Fig 4 Non-stop mode

4. Maintenance and Service

4.1 Cleaning

- 1) Mix water and mild detergent in proportion.
- 2) Wet a soft cleaning cloth in the mixture and squeeze out the excess water.
- 3) Clean the recorder with the damp cloth.

Note: The surface of the metal electrode is silver-plated, so it should only be wiped with water. After each use, wipe clean with a damp cloth to prevent from corrosion of the silver-plated surface.

4.2 Do Not Sterilize

For daily cleaning of the device surface, wipe the device with a clean cloth.

Note :

- Do not use any abrasive cleaner or organic solvents or detergent containing organic solvents (e.g. gasoline, alcohol, stain removers).
- Do not use any cleaning spray to clean the device. Under no circumstances should fluid be allowed to flow into the device.
- Disinfectants containing phenol compound and/or sodium chloride are corrosive and therefore not recommended.
- Be careful with using sanitizers (e.g. hand sanitizer) and high concentrations of alcohol (the mixture formed after evaporation is a flammable gas, which

can endanger the safety of electronic components).

- Do not autoclave.








4.3 Service

- Refer to section 4.5 Troubleshooting guide.
- For further assistance, please contact the after-sales service by phone or email as indicated in this manual.
- Please contact customer service before arranging for return or replacement of the device.

Note:

There is no preventive inspection or maintenance required for the ecgme device.

5. Explanation of symbols

Symbol	Description
	Type BF applied part
	Important, caution required, refer to the accompanying documents
	Waste Electrical and Electronic Equipment (WEEE). It is the user's responsibility to dispose this device at a designated collection point for recycling
	Manufacturer
	Year of Manufacture
SN	Serial Number
	Complies with the Medical Device Directive of the European Union
	Read instruction carefully before use

6. Troubleshooting Guide

Issue	Solution
Indicator light does not light up	Check both hands are in contact with the 2 electrodes.
	When the right hand holds the right electrode and the left side of the device in contact with the chest, if the light does not turn on, check the contact position is correct.
	If the skin is too dry, please wipe skin with alcohol wipes or moist cloth.
	If there is too much hair on the chest, please shave to make sure there is firm contact between electrode and skin.
	Check if the battery is out of power.
Does not start detection, always on hold	Check Bluetooth is turned on.
	Exit the detection page and re-enter.
	Restart Bluetooth.
Server does not return test results	Check the network connection.
	Check if your login is with guest account.
	Logout the current account and login again.

7. Warranty

Warranty Card

Product model and SN :

Name :

Date of purchase :

Retailer :

Contact Number :

Address :

Postal code :

Country:

8. Appendix

Guidelines and Manufacturer's Declaration - -- Electromagnetic Emission		
<p>ecgme is expected to be used in the following specified electromagnetic environment, and the user shall ensure that it is used in such an electromagnetic environment.</p>		
Emission test	Conformity	Electromagnetic environment -- Guidelines
RF Emission GB 4824	Group1	ecgme uses RF energy only for its internal functions. Thus, it has low RF emissions and little potential to interfere with nearby electronic equipment
RF Emission GB 4824	Type B	ecgme is suitable for use in all facilities, including domestic facilities and connection to the domestic residential public low voltage supply network
Harmonic Emission GB 17625.1	N/A	
Voltage fluctuation/ flicker emission GB 17625.2	N/A	

Guidelines and Manufacturer's Declaration -
--Electromagnetic Immunity

ecgme is expected to be used in the following specified electromagnetic environment, and the user shall ensure that it is used in such an electromagnetic environment

Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment --- Guidelines
Electrostatic discharge GB/T17626.2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The floor should be wood, concrete or tile, or at least 30% relative humidity if the floor is covered with a synthetic material
Electrical Fast Transient/Burst GB/T17626.4	±2kV to power line ±1kV to input/output lines	N/A	The power supply should have the quality for use in a commercial or hospital environment


<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>GB/T17626.11</p>	<p><5 % U_T, for 0.5 cycles (on U_T, >95% dip)</p> <p>40 % U_T, for 5 cycles (on U_T, 60% dip)</p> <p>70 % U_T, for 25 cycles (on U_T, 30% dip)</p> <p><5 % U_T, duration is 5s (on U_T, >95% dip)</p>	<p>N/A</p>	<p>The power supply should have the quality for use in a commercial or hospital environment.</p>
<p>Power frequency magnetic field (50/60Hz)</p> <p>GB/T17626.8</p>	<p>3A/m</p>	<p>3A/m</p>	<p>The power frequency magnetic field should have the characteristics of the power frequency magnetic field in a commercial or hospital environment</p>

Note: U_T refers to the AC network voltage before the test voltage is applied.

Guidelines and Manufacturer's Declaration ---
Electromagnetic Immunity

ecgme is expected to be used in the following specified electromagnetic environment, and the user shall ensure that it is used in such an electromagnetic environment

Immunity test	IEC 60601 Test Electrical Level	Compliance Electrical Level	Electromagnetic environment --- Guidelines
Conducted RF	3V (Effective Value)	3V/m	Portable or mobile RF communication devices should not be used closer to any part of the ecgme device (including the cable) than the recommended isolation distance. This distance is calculated by the formula corresponding to the transmitter frequency.

GB/T1 7626.6	150 kHz ~ 80MHz	3V/m	Recommended isolation distance:
Radiated RF			$d = 1.2\sqrt{P}$
GB/T1 7626.3	3V/m 80 MHz ~ 2.5GHz		$d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.5 GHz
			where: <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; <i>d</i> is the recommended separation distance in meters (m). The field strength of a fixed RF transmitter is determined by a survey of the electromagnetic field and should be lower than the compliance electrical level at each frequency range. Interference may occur in the vicinity of equipment marked with the following symbols.
			

Note 1: At 80 MHz and 800 MHz, the formula for the higher frequency range is used.

Note 2: These guidelines may not be applicable in all cases, electromagnetic transmission is influenced by absorption and reflection by constructions, objects and the human body.

Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts, etc., whose field strengths cannot be accurately predicted.

In order to determine the electromagnetic environment of fixed RF transmitters, a survey of the electromagnetic field should be considered.

If the field strength at the location of **ecgme** is measured to be higher than the applicable RF compliance electrical level, the **ecgme** should be observed to verify if it can operate properly.

If abnormal performance is observed, additional measures may be necessary, such as adjusting the orientation or location of **ecgme**.

The field strength should be less than 3 V/m over the entire frequency range of 150 kHz to 80 MHz.

Recommended separation distance between portable and mobile RF communication devices and **ecgme**

ecgme is expected to be used in an electromagnetic environment with controlled RF radiation interference. Based on the maximum output power rating of the communications equipment, the user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and **ecgme**.

The maximum output power rating of the transmitter (W)	Isolation distance corresponding to different frequencies of the transmitter /m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 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 maximum output power rating not listed in the table above, the recommended separation distance d , in meters (m), can be determined using the formula in the corresponding column of transmitter's frequency, where P is the maximum output power rating of transmitter in watts (W) provided by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the formula for the higher frequency band is used.

Note 2: Between 150kHz and 80MHz, the Industrial Scientific Medical (ISM) Band is 6.765MHz ~ 6.795MHz, 13.553MHz ~ 13.567MHz, 26.957MHz ~ 27.283MHz and 40.66MHz ~ 40.70MHz.

Note 3: The additional factor $10/3$ is used to calculate the recommended separation distance for transmitters that is in 150 kHz ~ 80 MHz ISM band and in the frequency range of 80 MHz ~ 2.5 GHz to reduce the possibility of interference caused by portable/mobile RF communication devices that are accidentally brought into the patient area.

Note 4: These guidelines may not be applicable in all cases, electromagnetic transmission is influenced by absorption and reflection by constructions, objects and the human body.



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