

PECG HC3A250
User Manual

1.Introduction:
HC3A250 is a miniature wearable dynamic PECG recorder. HC3A250 may be used to record from 1 minute to 48 hours PECG (or Holter monitoring), HC3A250 also has alert message function with alert message triggered by either panic button push, or heart beat stop. The HC3A250 should not be used for newborn baby weight less than 10kg. HC3A250 does not display pulse, or diagnostic function like heart rate algorithm and ST segment recognition function. The professional analysis ECG report (additional charge) would be provided by a third party.

Product basic information:
1)Product Name: PECG
2)Model: HC3A250
3)Production date: see the backside of the PECG
4)Expiry date: 3 years
5)Power: built-in rechargeable polymer lithium battery
Nominal voltage: 3.7V
Capacity 400mAh (1.48Wh)
6)Products and accessories:
a)1pc X PECG
b)12pcs X Single-use ECG electrodes
c)1 x USB data cable (connecting from PC to PECG)
d)1 x OTG USB Cable (connecting from mobile to PECG)
e)1 x Warranty card / user manual
f)1 x Certificate

Structure Description:

2.How to use :
(1)Preparing for device with electrodes
Put PECG in power-off state, assembly sticky patches called electrodes and remove the electrode protective films

(2)Wear PECG onto the chest
Prior to application of electrodes, suggested to shave or clean the body hair at electrode area (red oval area), thoroughly clean oily skin on the chest where the electrodes are placed, and keep the operation key of the PECG upward, and apply electrodes firmly to the skin. Make sure all electrodes are placed at site specified in the figure below, two electrodes in lower part of PECG should be placed on both sides of the chest wall where is nearly epigastric site.

(3)Open PECG to start recording
Switch on PECG, press & hold button till green led light on, after a couple of seconds, the green light will flash and PECG data collection starts immediately.

(4)Close PECG to stop monitoring
Switch off PECG, press & hold button continuously till green light on, after a few seconds, a green light flash turns off automatically, PECG data collection stops (normal use continuously 24 hours).

(5)Remove PECG from chest
When data collection stops, press ECG with a hand (see below diagram), remove electrodes from the chest slowly from outside to inside, and then pull out PECG & dispose of used electrodes into garbage bin. DON'T force to tear away electrodes from your chest to avoid any skin damage.

(7)Emergency Call: Push the “Switch” twice, yellow LED light will flash, the buzzer 3 times consecutively in 2 seconds, at the same time a short message would be sent to the emergency contact(s) via APP service. When push the Switch again, the buzzer stops the call.

(8)Heart Beat Stop Alarm: If the user occurs cardiac arrest heart beating for few seconds, will enter into an alarm state, PECG will trigger an emergency call for help, yellow LED light will flash, the buzzer sound 3 times consecutively in 2 seconds, at the same time a short message would be sent to the emergency contact via APP service. When push the Switch again, the buzzer stops the call.

3.Function Description:
PECG status description
PECG has three states: working, shut-down and charging / USB connection. When the PECG is in the shut-down state, press the “Switch” for about 3 seconds and the green light will be on for about 5 seconds, then PECG will enter the working state. When the PECG is in working state, press the Switch key for about 3 seconds. The green light will be on for 3-5 seconds and the PECG will enter in shut-down state. When the PECG is in working state or shut-down state, connect the USB data cable to the computer, which can enter the charging and USB connection state. When HC3A250 is in the charging / USB connection state, ECG data can not be collected. The following table is a detailed description of the three states:

Status name	Status description	Indicator light, buzzer reminder
Working state	When the PECG electrode is in good contact with the skin, the green light flashes once in 2 seconds;	When the PECG electrode is in good contact with the skin, the green light flashes once in 2 seconds;
	When the PECG electrode is in bad contact with the skin, the yellow light flashes once for about 2 seconds;	When the PECG electrode is in bad contact with the skin, the yellow light flashes once for about 2 seconds;
	The buzzer will sound once in 2 seconds when the battery is low.	The buzzer will sound once in 2 seconds when the battery is low.
	Once user heart beat stopped for few seconds, the PECG will trigger an “Emergency Call”, the buzzer will sound 3 times in 2 seconds. When push the switch again to cancel the “Emergency Call” & the buzzer sound.	Once user heart beat stopped for few seconds, the PECG will trigger an “Emergency Call”, the buzzer will sound 3 times in 2 seconds. When push the switch again to cancel the “Emergency Call” & the buzzer sound.
Shut-down state	Entering this state, ECG data collection stops	—
Charging / USB connection state	Entering this state, indicates that the PECG starts charging or charging while transferring data to the computer	During charging, the yellow light flashes once in 2 seconds. The green light stays green when fully charged or charging is complete.

The three state switching modes are shown below:

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graph TD
    Working[Working state] -- "Press and hold the key in 3 seconds" --> Shut-down[Shut-down state]
    Shut-down -- "Press and hold the key in 3 seconds" --> Working
    Shut-down -- "Connect the PECG to the PC/mobile phone with a USB data cable" --> Charging[Charging / USB connection state]
    Charging -- "Disconnect the PECG from the PC/mobile phone's USB connection" --> Shut-down
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Cautions :
◆ Please read the instructions carefully before using the PECG.
◆ Keep the PECG away from heat, moisture & water.
◆ Electrode is for one-time use only. Repeated use may cause skin infection.
⊗ Please do not disassemble and replace the battery, if necessary, please contact our authorized after-sales service department or dealer for processing.

4.Q & A:

Problem	Causes	Suggestions
Noisy waveform	Electrode does not make good contact with the skin caused by sweat, misplacement or reuse electrode	Make sure the chest skin is dry, clean and replace with new electrode
The computer does not detect the flash drive on the PECG after connection.	The computer may not have USB driver	Install USB driver in PECG
PECG device cannot connect with computer	USB cable may be damaged or does not have a good contact with computer	Use a new USB cable, pull out the cable from computer and re-connect again.
"TICK" sound from PECG	The battery is at a low power	Recharge the PECG device

Symbol:

	Fail to observe the warning may cause seriously injury or death to the user. May also cause the PECG to partial or completely damaged .
	Fail to observe the note may cause injury to the user. May also cause the PECG to work improperly.
	CF application part

5.Disclaimer:

● All data collected by PECG can not be used for medical diagnosis unless recognized by BISA authorized medical units, experts or doctors.
● The company will not take any responsibility for the misdiagnosis, misleading and loss caused by the self interpretation of the ECG data.
● The risk assessment based on ECG signals collected by ECG is not perfect. We will not take any responsibility for any loss caused by the Risk assessment which may affect user's health condition.
● The Company expressly disclaims any liability for loss of any direct, indirect or consequential damages caused by the PECG, including but not limited to loss of revenue, loss of profits, business interruption or loss of data, regardless of any form of action or legal claim of the liability, and even including any prior notice of any loss incurred.

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動態心電記錄儀HC3A250
操作說明書

1.功能和預期用途:
HC3A250是一種微型可穿戴式動態心電記錄儀，用於人體1分鐘～48小時的動態心電監測，其功能相當於Holter。有主動求助和心跳停搏時報警功能。不能用於記錄體重低於10kg的新生兒心電圖，不具有起搏脈衝顯示能力。HC3A250不包括自動分析診斷、心律演算法和ST段識別功能。專業心電分析報告(另收費)由第三方提供。

產品基本資訊:
1) 產品名稱: 動態心電記錄儀
2) 產品型號: HC3A250
3) 生產日期: 見主機背面銘牌
4) 有效期限: 3年
5) 電源: 內置可充電聚合物鋰電池
標稱電壓: 3.7V
容量400mAh (1.48Wh)
6) 產品及配件:
a) 動態心電記錄儀1台
b) 一次性使用心電電極片 12片
c) USB資料連接線1條 (連接電腦和動態心電記錄儀)
d) OTG USB資料連接線1條 (連接手機和動態心電記錄儀)
e) 說明書/保修卡1本
f) 合格證1張

結構說明:

2. 如何使用 :
(1) 安裝一次性使用心電電極片
取出一台處於關閉狀態的動態心電記錄儀，將電極片與動態心電記錄儀四角對齊合併揭去電極片保護膜。

(2)貼載動態心電記錄儀
建議剝掉在電極片安放位置（紅色橢圓區域）的體毛，徹底清潔電極片安裝位置的皮膚上的油脂和污垢，保持動態心電記錄儀的操作鍵朝上的方向，將一次性使用心電電極片緊密貼合皮膚，把電極片貼在圖中橢圓圈指定的位置，靠近心窩部兩側。

(3) 開始採集資料
啟動動態心電記錄儀，長按操作鍵直至指示燈顯示為綠色，數秒後指示燈開始閃爍，採集數據開始。

(4) 結束採集資料
待資料獲取結束後（一般為24小時），關閉動態心電記錄儀，長按操作鍵直至指示燈顯示為綠色，數秒後指示燈熄滅，採集數據結束。

(5) 取下動態心電記錄儀
採集數據結束後，用手按著動態心電記錄儀，如下圖所示，從電極片的A處開始，然後由外向內慢慢揭下一次性使用心電電極片，放下動態心電記錄儀，然後拔開電極片，將電極片棄置垃圾桶。取下時切勿用力撕扯電極片，以免損傷皮膚。

(6) 上傳數據
將動態心電記錄儀通過OTG資料線連接手機或者通過USB資料線連接電腦，上傳動態心電記錄儀資料請參考本公司官網最新說明書。

**本公司一次性使用心電電極片已通過生物性相容測試，若用戶佩戴一次性使用心電電極片後出現皮膚不適或紅腫，請立即停止使用並取下動態心電記錄儀。若有需要，請前往醫院就醫。

3.功能說明

動態心電記錄儀狀態說明
動態心電記錄儀有三個狀態：工作狀態、關閉狀態、充電/USB連接狀態。當動態心電記錄儀處於關閉狀態時，長按操作鍵約3秒，綠燈會長亮約5秒，然後進入工作狀態。動態心電記錄儀處於工作狀態時，長按操作鍵約3秒，綠燈會長亮3～5秒，然後進入關閉狀態。動態心電記錄儀處於工作狀態或者關閉狀態時，使用USB資料線連接開機的電腦即進入充電/USB連接狀態。
動態心電記錄儀在充電/USB連接狀態下不能採集心電數據。

以下表格為三個狀態的詳細說明：

狀態名稱	狀態說明	指示燈、蜂鳴器提醒
工作狀態	進入此狀態動態心電記錄儀即開始採集數據	此狀態下電極片與皮膚接觸良好時，綠燈約2秒閃爍一次； 此狀態下電極片與皮膚接觸不良時，黃燈約2秒閃爍一次； 此狀態下低電量時蜂鳴器約2秒鳴叫一次
	此狀態下使用發生停搏時蜂鳴器約2秒鳴叫3次，此時再按一下操作鍵則取消報警，蜂鳴器停止鳴叫。	此狀態下使用發生停搏時蜂鳴器約2秒鳴叫3次，此時再按一下操作鍵則取消報警，蜂鳴器停止鳴叫。
	此狀態下連接2下操作鍵觸發主動求助，蜂鳴器約2秒鳴叫3次，同時將短信發給緊急聯絡人（在有提供APP服務情況下）。此時再按一下操作鍵則取消求助，蜂鳴器停止鳴叫。	此狀態下連接2下操作鍵觸發主動求助，蜂鳴器約2秒鳴叫3次，同時將短信發給緊急聯絡人（在有提供APP服務情況下）。此時再按一下操作鍵則取消求助，蜂鳴器停止鳴叫。
	此狀態下連接2下操作鍵觸發主動求助，蜂鳴器約2秒鳴叫3次，此時再按一下操作鍵則取消求助，蜂鳴器停止鳴叫。	此狀態下連接2下操作鍵觸發主動求助，蜂鳴器約2秒鳴叫3次，此時再按一下操作鍵則取消求助，蜂鳴器停止鳴叫。
關閉狀態	進入此狀態動態心電記錄儀將停止採集數據	—
充電/USB連接狀態	進入此狀態表示動態心電記錄儀開始充電，在充電的同時與電腦進行數據傳輸	充電未完成時黃燈約2秒閃爍一次 充電完成時綠燈長亮

三個狀態切換方式如下圖所示：

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graph TD
    Working[工作狀態] -- "長按操作鍵約3秒" --> Shut-down[關閉狀態]
    Shut-down -- "長按操作鍵約3秒" --> Working
    Shut-down -- "用USB資料線連接心電儀與電腦或手機" --> Charging[充電/USB連接狀態]
    Charging -- "斷開動態心電記錄儀與電腦/手機的连接" --> Shut-down
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注意事項
1.在使用動態心電記錄儀前請仔細閱讀說明書。
2.請將電極片放置在遠離高溫、潮濕和水浸的地方。
3.電極片為一次性消耗品，重複使用可能導致發炎或感染。
⊗ 請勿自行拆卸和更換電池，若有需要，請聯繫本公司授權的售後維修部門或經銷商進行處理。

4.常見的問題和解決方法

問題現象	可能原因	排除方法
心電圖波形紊亂	電極片與皮膚粘貼不良、出汗導致電極片脫落、重複使用電極片	確保胸口皮膚乾燥清潔再更換新的電極片
動態心電記錄儀與電腦連接不上，但不會出現提示	電腦未安裝動態心電記錄儀的USB驅動程式	安裝動態心電記錄儀的USB驅動程式
動態心電記錄儀與電腦連接不上	數據線損壞、USB與電腦接觸不良	更換新的資料數據線、拔下USB資料線與電腦重新連接（對於桌式電腦建議直接使用主機背面的USB口）
動態心電記錄儀發出“滴”聲	動態心電記錄儀處於低電壓狀態，提示使用者充滿電再使用	給動態心電記錄儀充滿電再使用

符號:

	警告	如果無視本標識而使用時，有可能造成死亡或者重傷，也可能造成本儀器的部分或全部損壞。
	注意	如果無視本標識而使用時，有可能造成人員受傷，造成本儀器的損壞或使用效果不理想。
	CF型應用部分	

5.免責聲明

● 本公司產品採集的心電資料只有經過本公司授權的醫療單位、專家或醫生解讀才能用於醫療診斷。
● 使用者對於本公司產品採集的心電資料的自我解讀所造成的誤診誤導和損失，本公司不承擔任何責任。
● 依據本公司產品採集的心電資料所做的風險評估並非完美。由於風險評估的指數偏高導致用戶心理負擔加重從而可能造成病情的惡化或由於風險評估的指數偏低但用戶實際病情的惡化等情況而造成的損失，本公司不承擔任何責任。
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