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

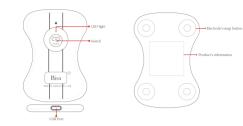
b)12pcs X Single-use ECG electrodes c)1 x USB data cable (connecting from PC to PECG)

d)1 x OTG USB Cable (connecting from mobile to PECG)

e)1 x Warranty card / user manual

f)1 x Certificate

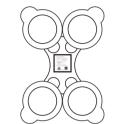
Structure Description:



2.How to use

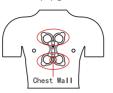
(1)Preparing for device with electrodes

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

on, after a few seconds, a green light flash turns off automatically, PECG data collection stops (normal use continuously 24 hours).

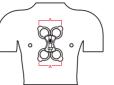
5)Remove PECG from chest

When data collection stops, press ECG with a hand (see below diagram), starting from point "A", 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.



the PECG to the mobile phone through the OTG cable or connect the computer via the USB cable. How to unload the PECG data, Please refer to www.bisahealth.com for details.

Switch off PECG, press & hold button continuously till green light



6)Upload data by mobile phone or PC

After data collection completed, remove the PECG and connect

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.

		* '
		When the PECG electrode is in good contact with the skin, the green light flashes once in 2 seconds;
	Enter this state, PECG data collection starts	When the PECG electrode is in bad contact with the skin, the yellow light flashes once for about 2 seconds;
Working state		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.
		In this state, press the Switch key twice to trigger stop to help, the buzzer consecutively 3 times in 2 seconds, then press the operation button to cancel the alarm, the buzzer stops call.
Shut-down state	Entering this status, ECG data collection stops	
Charging / USB	Entering this state, indicates that the PECG starts charging	During charging, the yellow light flashes once in 2 seconds.
connection state	or charging while transferring data to the computer	The green light stays green when fully charged or charging is complete.

PECG to the

PC/mobile

nhone with

a USB data

Cautions:

skin infection

dealer for processing.

The following table is a detailed description of the three states:

Working state	Enter this 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 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.
	PECG data collection starts	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.
		In this state, press the Switch key twice to trigger stop to help, the buzzer consecutively 3 times in 2 seconds, then press the operation button to cancel the alarm, the buzzer stops call.
Shut-down state Entering this status, ECG data collection stops	status, ECG data	
Charging / USB	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.
connection state		The green light stays green when fully charged or charging is complete.

Status name Status description Indicator light, buzzer reminder

4.0 & 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:

	Marning	Fail to observe the warning may cause seriously injury or death to the user. May also cause the PECG to partial or completely damaged .
	<u>∱</u> Note	Fail to observe the note may cause injury to the user. May also cause the PECG to work improperly.
•		CF application part

notice of any loss incurred. Contact us

5.Disclaimer:

doctors

Email: <u>bisapecg@bisa.com.hk</u> Website: www.bisahealth.com



All data collected by PECG can not be used for medical diagnosis.

unless recognized by BISA authorized medical units, experts or

• The company will not take any responsibility for the misdiagnosis,

• The risk assessment based on ECG signals collected by ECG is not

the Risk assessment which may affect user's health condition.

direct, indirect or consequential damages caused by the PECG.

business interruption or loss of data, regardless of any form of

action or legal claim of the liability, and even including any prior

• The Company expressly disclaims any liability for loss of any

including but not limited to loss of revenue, loss of profits,

perfect. We will not take any responsibility for any loss caused by

misleading and loss caused by the self interpretation of the ECG

動熊心電記錄儀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:

) 產品名稱: 動態心電記錄儀

) 產品型號: HC3A250) 生產日期: 見主機背面銘牌

) 有效期限·3年 電源:內置可充電聚合物鋰電池

標稱電壓: 3.7V

容量400mAh (1.48Wh)

) 產品及配件:

a) 動態心電記錄儀1台

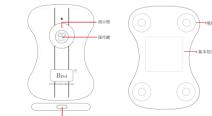
b) 一次性使用心電電極片 12片

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

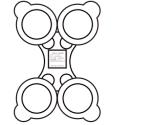
結構說明



如何使用:

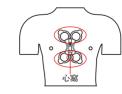
(1) 安裝一次性使用心電電極片

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扣合併揭去電極片保護膜。



(2) 貼戴動態心電記錄儀

建議剃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 用心電電極貼片緊密貼合皮膚, 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



(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,上傳動熊心電記錄儀資料請參考本公司 官網最新說明書。

)緊急求助操作

動態心電記錄儀在採集狀態下連按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連 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。

7)Emergency Call: Push the "Switch" twice, yellow LED light will

same time a short message would be sent to the emergency

contact(s) via APP service. When push the Switch again, the

8)Heart Beat Stop Alarm: If the user occurs cardiac arrest heart

beating for few seconds, will enter into an alarm state, PECG

flash, the buzzer sound 3 times consecutively in 2 seconds, at

will trigger an emergency call for help, yellow LED light will

emergency contact via APP service. When push the Switch

Note: This electrode has passed biological evaluation of

medical devices, but electrodes may cause some users like

irritation, itchy or rashes to your skin, such users must stop

using it immediately, remove electrodes and take out ECG,

consult doctors for medical treatment if needed.

the same time a short message would be sent to the

buzzer stops the call.

again, the buzzer stops the call.

flash, the buzzer 3 times consecutively in 2 seconds, at the

(8) 停搏提醒

動態心電記錄儀在採集狀態下, 若使用者發生心臟停搏 事件動態心電記錄儀會觸發停搏求助、蜂鳴器約2秒鳴 叫3次,同時將短信發給緊急連絡人(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。

**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。

狀態名稱 狀態說明 指示燈、蜂鳴器提醒

以下表格為三個狀態的詳細說明:

	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;		
工作狀態		此狀態下低電量時蜂鳴器約2秒鳴叫一次		
工作水忠		此狀態下使用者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。		
		此狀態下連按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	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		
連接狀態		充電完成時綠燈長亮		

三個狀態切換方式如下圖所示:

The three state switching modes are shown below:

◆ Please read the instructions carefully before using the PECG.

◆ Electrode is for one-time use only. Repeated use may cause

Please do not disassemble and replace the battery, if necessary, please contact our authorized after-sales service department or

◆ Keep the PECG away from heat, moisture & water.



- 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

ı	問題現象	可能原因	排除方法	
l	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	• 1
l	動態心電記錄儀與電腦連 接上,但不會出現盤符	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	• 1
	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 (對於臺 式電腦建議直接使用主機背面的 USB口)	j
۱	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:

<u>♠</u> 警告	如果無倪本標識而使用時, 有可能這成死 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 亞位、專家或醫生解讀才能用於醫療診斷。
- 日用者對於本公司產品採集的心電資料的自我解讀所造 的誤診誤導和損失, 本公司不承擔任何責任。
- 衣據本公司產品採集的心電資料所做的風險評估並非完 。由於風險評估的指數偏高導致用戶心理負擔加重從 可能造成病情的惡化或由於風險評估的指數偏低但用 寶際病情的惡化等情況而造成的損失,本公司不承擔 4何青任。
- ●本公司明確表示不對任何直接、間接或相關情況導致的 損失負責,包括但不限於收入損失、利潤損失、業務中 斷或資料丟失而帶來的損失,無論任何形式的行動或法 律原則下的所宣稱的賠償責任, 甚至包括事先已告知任 何可能導致的損失。

●聯絡我們

公司郵箱: _bisapecg@bisa.com

公司網站: www.bisahealth.com



