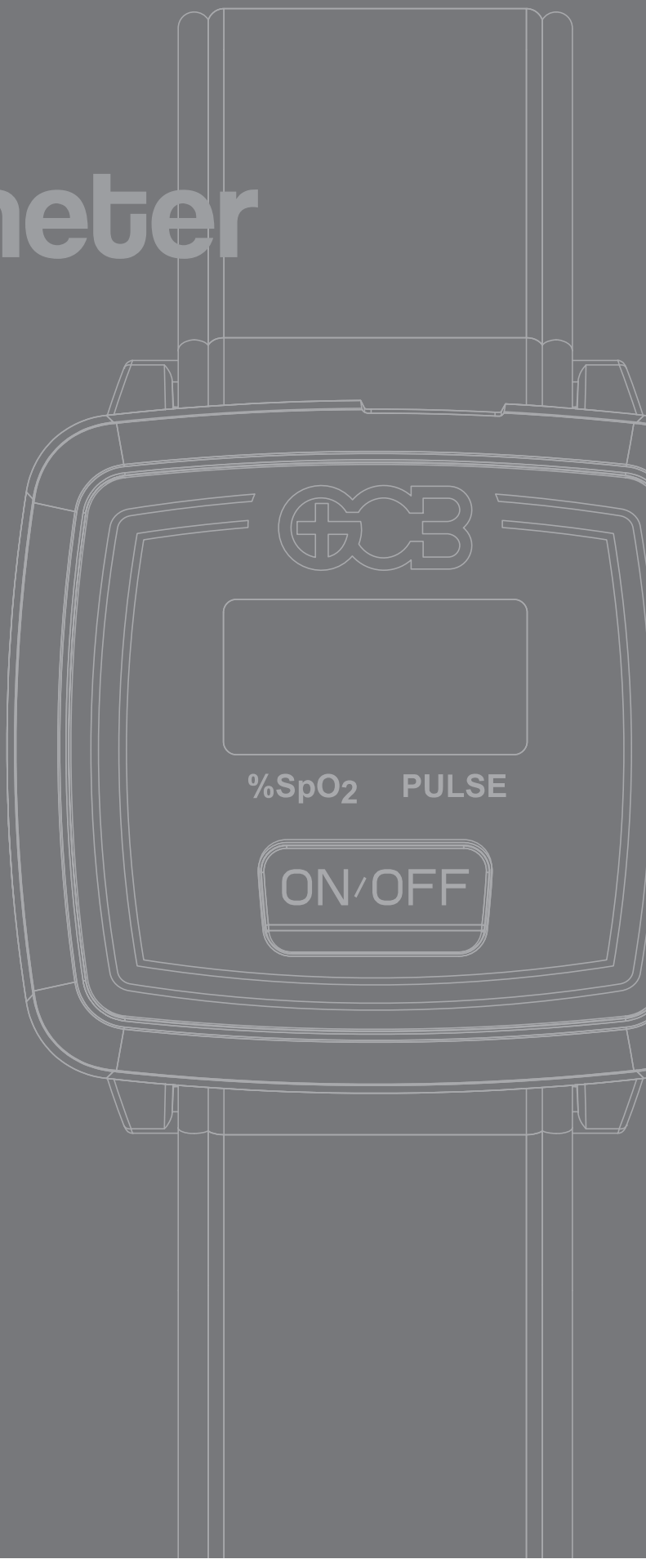
GCB
Pulse Oximeter

:: 藍牙脈搏血氧儀 ::



User Manual
使用說明書

| Model 產品型號 GCB-X001 |

目錄檢索 GCB Pulse Oximeter

< 說明 >

本說明書對**藍牙脈搏血氧儀**(以下簡稱血氧儀)使用進行說明。在使用之前，請認真閱讀並理解本說明書中的內容，以保證能夠正確的使用產品，發揮其最佳性能，並確保受測者和操作者之安全。
請將本說明書放置於本血氧儀附近，以便需要時能即時獲取。本說明書內容如有變動，在不涉及使用者正常使用情況下恕不預先通知。

免責聲明

❶ GCB僅就本公司產品之維修與檢測負責，未提供產品內儲存資料的修復、救援或備份服務，具備儲存功能之產品，在送修前請先將所有資料自行備份或刪除。任何造成送修產品內所儲存的資料遺失，或送修之運送過程中因任何因素造成之產品不良或損壞及資料遺失，本公司不負任何責任。

❷ 在適用法律允許的最大範圍內，任何因使用本公司產品所致使有關之營利損失、預期成本損失、資料遺失、或其他間接、意外或衍生性之損失或損傷，本公司不負任何賠償責任。

❸ 本公司產品為個人血氧監測裝置，並不適用於急重症使用者合併生命維持設備的結合使用；若將該產品併用於該生命維持設備中而造成相關人員的傷害及財損，GCB公司將不負擔任何法律責任。包括但不限於: 軍事設備或軍事相關設備、航空器、交通控制設備、災害預防系統，燃燒控制系統、核能設備以及醫療設備或醫療相關設備等。

產品保證

產品保修條款

GCB針對其全系列產品保證無材質及設計上的問題。在正常使用的情況下，若證實因產品材質設計或不適當之製作，而造成產品瑕疵，將遵循以下條款及限制規範，提供產品修復、更換產品零件或更換同等級產品的方式進行保固。

GCB得於檢視產品後，判定給予維修或更換新品或良品，或以功能近似之產品替代。因履行本保固服務所更換之原產品或原零件將不予歸還 (包含付費維修的情況)。因本保固服務而更換之新品、良品或功能近似之替代產品，其保固期間應以送修品所享有之剩餘期間為准。所有經過維修或更換的產品在返還前均已通過測試，確保其功能正常等同於新品。針對不適用本保固服務之產品，GCB得拒絕檢視、維修或更換零元件，如最終決定提供相關服務，將酌收相關費用。

保固服務

在正常使用的狀況下，產品因非人為因素而損壞，本裝置享有一年產品保固。

有限保固

❶ 由於產品生命週期更替快速，若在產品保固年限之內，所購買的產品宣告停產，GCB得自行決定修復產品或以同等級近似產品更換之。

❷ 針對已過保固期限或者上述不符合本保固服務範圍之事項，GCB得拒絕檢視、維修或更換零元件，若最終決定提供相關服務，將可能收取相關費用。

❸ 部份產品之維修可能採用更換方式作業，故維修後之產品可能非原本送修品。

保固範圍

本保固服務僅限於透過合法銷售通路購買GCB產品的原始一般客戶，並不適用於二手轉賣授讓，或其他未經事前書面同意而利用本保固服務為自己或他人營利之行為。對於二手收購之產品、非經授權同意通路之產品、保固標籤被撕毀而造成無法辨識產品真偽、以及判定為仿冒假品者，本公司有權拒絕提供任何產品保固服務。

❶ 在正常操作使用狀態下，若判定為產品本身品質問題而影響使用，只要產品無外觀損壞且在保固期限內，均享有免費維修或者更換產品的服務。

❷ 本產品保固條款之適用範圍，不涵蓋任何因為不當安裝、意外、濫用、誤用、天然災害、電力供應不足，或過度、不正常的機械或環境狀態所造成之故障。
包括 (但不僅限於) 下列狀況：

- **i.** 因外力或人為不當操作所造成，並非產品本身之故障因素
- **ii.** 未經本公司授權之技術人員而將產品拆裝或維修
- **iii.** 保固 / 防拆標籤被損毀、更改、或遺失
- **iv.** 產品序號破損、不清楚或不符合原廠出廠序號
- **v.** 透過非正式授權或非合法銷售管道所購買之產品
- **vi.** 因使用環境或保存不當，造成產品腐蝕、生銹等現象
- **vii.** 因運輸不良或其他不可抗力因素造成產品損壞

❸ 在保固期限內，如因人為因素而造成產品損壞影響使用 (含產品外觀性損壞)，經GCB測試判定之後，如會影響產品正常功能，原廠有權不予維修或報價維修 (報價維修費用需由消費者承擔)。 包括 (但不僅限於) 下列狀況：

- **i.** 電路板上有劃痕或裂痕
- **ii.** IC顆粒損壞或脫落 (1–2顆以內)
- **iii.** IC顆粒損壞或脫落，損壞超過3顆及以上，不予維修
- **iv.** PCB板完全斷裂，不予維修
- **v.** 未經GCB同意，擅自拆解或使儀器設備修改記憶體參數或其他未列舉嚴重損壞且影響產品功能者，原廠有權拒絕維修。

1 安全資訊

本章列出了操作使用本血氧儀時，用戶應當注意和遵守的基本安全警示資訊。

警告：

① 使用本血氧儀的相關人員，在使用前必須接受充分的訓練。
② 本血氧儀是一種監測設備，不是治療設備，使用時應該結合具體的臨床症狀。
③ 在使用本血氧儀之前，使用者應檢查並確保儀器及附件能正常安全工作。
④ 本血氧儀與電外科設備共用時，使用者應注意並保證被監測者的安全。
⑤ 切勿在放有麻醉劑等易燃物品的地方使用本血氧儀，以防發生火災或爆炸。
⑥ 本血氧儀不能在磁共振成像掃描系統 (MRI) 和電腦斷層掃描 (CT) 中使用。
⑦ 本血氧儀不具有報警功能，不適用於長期連續監護。
⑧ 使用時應保證被測量部位沒有污物或者傷口。
⑨ 請使用本血氧儀配套或者經製造商許可的附件、血氧飽和度感測器和電纜線。使用前請務必檢查確認血氧飽和度感測器與本血氧儀的相容性。如果使用未指定的附件、血氧飽和度感測器和電纜線，可能增強電磁輻射或降低抗電磁干擾性能。
⑩ 清潔本血氧儀和附件之前，請先關閉電源。
⑪ 本血氧儀為普通的密封式設備，使用者應保證其表面乾燥清潔，並防止任何液體進入內部。
⑫ 用戶應妥善放置本血氧儀，防止其從高處墜落、受到強烈的震盪或其他機械外力的損壞。
⑬ 不得擅自更改本血氧儀及附件，其維修應由製造商認可的專業維修人員進行。
⑭ 嚴禁擅自拆除與更換內部的鋰電池，當電池電量較低時，請及時充電。
並應定期將電池充電，但切勿過度充電。
⑮ 為避免污染或感染他人、環境或其他設備，在報廢本血氧儀及附件之前，請按照報廢相關規定對本血氧儀以及附件進行報廢處理。
⑯ 如果配套本血氧儀使用的附件是一次性使用的，使用後請及時按照相關規定進行報廢處理，僅用於單一患者，嚴禁二次使用。
⑰ 本血氧儀設備經校準顯示功能血氧飽和度。

⑱ 應避免靜電產生，使用本血氧儀前，確認所有與儀器接觸的操作者和受測者之直接或間接的靜電。

⑲ 使用時，應儘量使本血氧儀遠離無線電接收器。

⑳ 本血氧儀如使用未指定且未經 EMC 試驗系統組態，可能增強電磁輻射或降低抗電磁干擾性能，請限用指定配置。

㉑ 可攜式和移動式射頻通信設備可能影響本血氧儀的正常使用。

㉒ 本血氧儀不應與其它設備接近或疊放使用，如果必須接近或疊放使用，則應觀察驗證在其使用的配置下能正常運行。

㉓ 除本血氧儀的製造商作為內部元器件的備件出售的附件和電纜外，使用規定外的附件和電纜可能導致設備或系統發射的增加或抗擾度的降低。

注意：

① 使用本產品之前，請仔細閱讀本說明書、所有的安全資訊及技術規格。

② 國家通訊傳播委員會(NCC)警語：低功率電波輻射性電機管理辦法

第十二條　經型式認證合格之低功率射頻電機，非經許可，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。

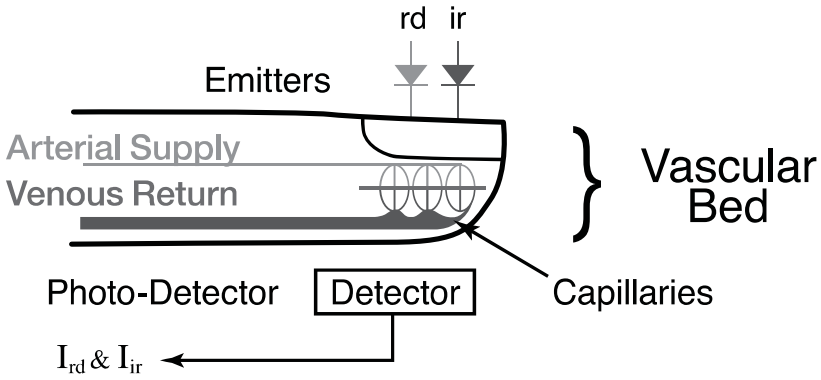
第十四條　低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。
前項合法通信，指依電信法規定作業之無線電通信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

2 測量原理

採用**脈動血氧定量法**，依據血紅蛋白和氧合血紅蛋白對不同波長的光線吸收的不同，即**分光光度原理**。感測器內光源發射光線穿過受測者組織到達另一方的接收器，並測定光線之多寡。穿過的光線數量取決於多種因素，其中大多數是恒定的，但因動脈血流是脈動的，故隨時間有規律的變化。血氧儀通過測定脈動期間吸收的光線，在獲得容積波、脈率和脈搏強度的同時，即得知動脈血液的氧飽和度，經儀器處理並將數值顯示於螢幕。

◎ 感測線波長範圍
→ 660~905 nm

◎ 最大光輸出功率
→ 2.0 mW



3 產品特點

① 使用簡單方便，可一鍵操作。
② 體積小、重量輕，攜帶方便。
③ 產品功耗低，所配 3.7V 鋰電池可持續使用 12 小時。
④ 在無信號產生時，該產品會在 10 分鐘後自動關機。
⑤ 無需日常維護和校準。
⑥ 可通過藍牙與手機或電腦等設備實現通訊。

4 適用範圍

適用於醫療機構及家庭護理中估算監測成年人體動脈血氧飽和度和脈搏。

5 禁忌症

與血氧飽和度感測器接觸的測量部位皮膚組織不得有損傷，且建議一次在同一位置連續使用時間不要超過8小時。

6 產品組成

① 脈搏血氧儀本體 x1

② 腕帶 x1

③ 拋棄式血氧飽和度感測線 x1
(滅菌包裝) 選配

④ USB充電線 x1 選配

⑤ 使用說明書 x1

7 產品規格

顯示模式	OLED 液晶螢幕	**電池**	3.7V 鋰離子充電電池
產品本體尺寸	57 (長) × 53.6 (寬) × 15.2(高) mm	**工作電壓**	D.C. 3.4V～D.C.4.3V
產品重量	47g (不包含探測線)	**工作電流**	小於 50mA

血氧飽和度 (SpO_2)

測量範圍	35～100%	
測量解析度	1 %	
測量準確度	80%～100%	誤差 ±2%
	70%～ 79%	誤差 ±3%
	70% 以下	不定義

脈率 (PR)

測量範圍	25～250 bpm
測量解析度	1 bpm
測量準確度	±2 bmp 或者 ±2% 二者應取絕對值大者

8 操作說明

① 測量之前，應檢查血氧儀、血氧飽和度感測器及其電纜是否正常，如果有受損現象，請不要使用。

② 醫療設備請小心地連接線纜，避免受測者被纏繞或產生窒息的情況。

③ 電外科設備的電纜不能與血氧飽和度感測器的電纜纏繞在一起。

④ 勿將血氧飽和度感測器放在有動脈導管或靜脈注射管的肢體上。

⑤ 勿將血氧飽和度感測器與血壓測量放在同一肢體上，因為血壓測量過程中血流閉塞會影響血氧飽和度的讀數。

⑥ 本血氧儀不能監測脈率低於30bpm之受測者，否則可能致不準確的PR結果。

⑦ 測量部位應儘量選擇灌注良好並且能夠完全覆蓋感測器探測窗的部位，在安放血氧飽和度感測器之前須先清潔測量部位，並保證乾燥。

⑧ 強光會導致測量不準確。若光線較強，應用不透光材料遮蓋感測器。

⑨ 應保證被測量部位沒有污物或傷疤，否則檢測出的血氧信號可能有過低之情況，導致血氧測量值不準確。

⑩ 本血氧儀在不同的受測者間使用時，可能出現交叉感染，用戶應注意預防和控制，建議在不同受測者間使用前應對血氧飽和度感測器進行清潔或消毒處理。

⑪ 血氧飽和度感測器測量部位應避免頻繁移動，應儘量使病人保持安靜，減少移動，尤其是測量部位。

⑫ 血氧飽和度感測器安放位置不當可能影響測量的準確性，當感測器與心臟在同一水平位置時，測量效果最佳。

⑬ 應根據不同的受測者及測量部位選擇合適的血氧飽和度感測器。
感測器太緊將會導致靜脈脈動、血液迴圈受阻、壓迫痕跡、壓迫性壞死、偽差、測量不準確；如果太鬆就會有損光學對準，甚至會脫落的情況；如果因為安放位置過大，或是由於安放部位水腫變大，導致感測器太緊，過大的壓力就會在安放部位的遠端導致靜脈淤血，造成間質水腫和組織缺血。

⑭ 電池充電操作方式：

i. 將Mini USB充電線插入裝置的USB連接口

ii. 充電時，OLED電池圖標顯示如下

iii. 充滿電時，OLED電池圖標顯示如下

iv. 請勿使用於易產生靜電電磁場干擾之環境

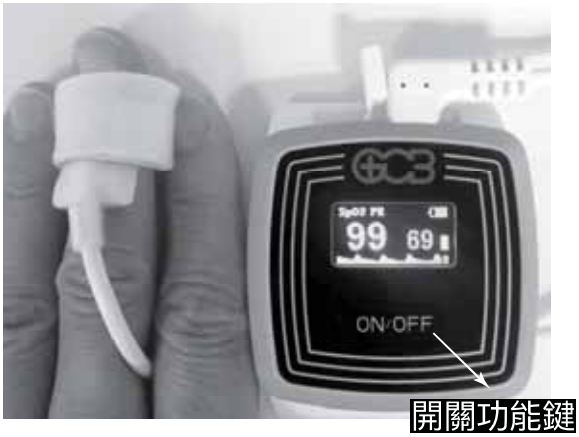
⑮ 當感測線未妥善連接時，裝置會呈現待測模式狀態，如下圖所示。

9 測量步驟

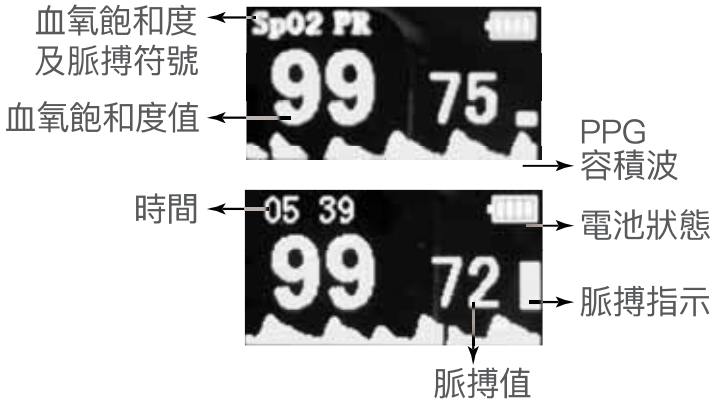
① 將血氧飽和度感測器的Mini USB插頭插入到血氧儀相應的插座中。

② 打開血氧儀電源，OLED顯示幕出現待測介面。

③ 將血氧飽和度感測器安放在受測者身上之適當部位。



④ 稍待片刻，即可從 OLED 顯示幕上讀取資料。



⑤ 顯示幕中的血氧值及脈搏值，每秒刷新一次；按壓一次“開/關”鍵則切換至時間顯示 (再按壓一次“開/關”鍵則回復為SpO_2 PR符號顯示)。

⑥ 為了要產生確定的測試記錄，須保持量測模式 15 分鐘以上。

⑦ 為了節省電池電力消耗，血氧儀螢幕會於 1 分鐘後自動關閉。
按壓一次“開 / 關”鍵則螢幕再次開啟。

⑧ 若於待機模式下持續超過 10 分鐘，則血氧儀會自動關機。

⑨ 在待機或量測狀態下長按“開 / 關”鍵 3 秒，則系統關機。

⑩ 量測完畢後，資料會儲存於血氧儀中；可將血氧儀內所儲存之量測資料經由藍牙傳輸至您的個人裝置上。若您要使用此功能，請先與您的經銷商聯繫。

10 清潔與消毒

❶ 不可將本血氧儀及附件浸泡在水中或消毒劑中。
❷ 頻繁的針對本血氧儀及血氧飽和度感測器進行消毒會對其造成傷害。
❸ 僅使用本說明書中指定的清潔劑和消毒劑。
❹ 不得對本血氧儀及附件進行高壓、高溫消毒，在清潔或消毒本血氧儀及附件前必須關閉血氧儀電源。

清潔：

① 用沾有清水的棉球或者軟布擦拭本血氧儀或血氧飽和度感測器。
② 清洗完畢後，先用布將本血氧儀或血氧飽和度感測器擦乾。
③ 將本血氧儀或血氧飽和度感測器放置在陰涼的環境下晾乾。

消毒：

① 推薦使用的消毒劑包括：70%乙醇、70%異丙醇、2%戊二醛溶液。
② 消毒前，先清潔本血氧儀或血氧飽和度感測器。
③ 用棉球或軟布沾取適量的消毒劑，擦洗本血氧儀或血氧飽和度感測器。
④ 用沾有清水的軟布擦出殘留在本血氧儀或血氧飽和度感測器上的消毒劑。
⑤ 將本血氧儀或血氧飽和度感測器放置在陰涼的環境下晾乾。

11 環境要求

● **溫度範圍**

作業環境	+5 ～+35℃
運輸與儲存	–10～+50℃

● **相對濕度範圍**

作業環境	15%～80%(無凝結)
運輸與儲存	10%～90%(無凝結)

● **大氣壓範圍**

作業環境	860hPa～1060hPa
運輸與儲存	700hPa～1060hPa

12 故障排除

❓ 血氧值或脈搏值不能正常顯示或測量值消失

① 可能是手指放置位置不當導致，請將手指放入血氧飽和度感測器適當位置以重新測試。

② 可能為受測者之血氧飽和度值低至無法被測量。
在產品無損壞前提下，測量多次仍無法顯示，請及時至醫院就診。

③ 請檢查血氧飽和度感測器的插頭是否鬆動或脫落。

❓ 血氧值或脈搏值顯示不穩定

① 可能手指放入得不夠深，以致無法精準測量，請將手指正確放入血氧飽和度感測器適當位置以重新測試。

② 若手指抖動或受測者處於運動狀態易使數值顯示不穩定，使用血氧儀過程中盡量保持靜止及安靜狀態。

❓ 血氧儀無法開機

① 請檢查電池電量是否不足或耗盡，即時充電。

② 可能產品已損壞，請與當地的客戶服務中心聯繫。

❓ 顯示螢幕突然熄滅

① 本產品設定為偵測不到信號會在10分鐘後自動關機，屬正常情況。

② 請檢查電池電量是否不足或耗盡，即時充電。

13 標示符號說明

SN 產品序號	藍牙
參考使用手冊： 使用裝置前請參考使用說明	注意事項。請仔細閱讀文字內容 以便安全使用本裝置
內容物可以且必須回收使用	此儀器不帶有報警功能
直流電	製造商
電子電機設備分類回收 (WEEE)	IP22 外殼防護等級

Type BF保護等級：
應用的郵件可以連接到使用者的身體，允許與其它接觸部分連接到使用者。

14 棄置處理說明

本符號表示產品為電器設備，如需棄置時請按產品使用地區的環保法規處理。

終

Declaration of Conformity

For IEC 60601-1-2 (3rd Ed.)

Company Name: Taiwan Green Cross Co., Ltd.

Company Address: 6F., No. 244, Sec. 3, Chengteh Road, Taipei, 10367, Taiwan, R.O.C.

Trade Name: GCB

Report Number: 20-02-RBO-025

Power Supply: Battery Pack: 3.7V, 720mAh

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The GCB Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GCB Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GCB Pulse Oximeter 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 $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.67	11.67	23.33

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are LIFE-SUPPORTING

The GCB Pulse Oximeter declaration – electromagnetic immunity

The GCB Pulse Oximeter system is intended for use in the electromagnetic environment specified below.
The customer or the user of the GCB Pulse Oximeter system should assure that it 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 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m ; 10 V/m 80 MHz to 2.5 GHz	10 V/m	

Declaration – electromagnetic immunity

The GCB Pulse Oximeter system is intended for use in the electromagnetic environment specified below.
The customer or the user of the GCB Pulse Oximeter system 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic emissions

The GCB Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the GCB Pulse Oximeter should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The GCB Pulse Oximeter 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 GCB Pulse Oximeter 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	N/A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	N/A	

Contents

GCB
Pulse Oximeter

Instructions

This manual provides the instructions necessary to operate GCB Pulse Oximeter in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures testee and operator safety. Content of this manual is subject to change without prior notice.

Disclaimer

❶ Never does this Warranty apply to the recovery or back-up of any digital data from within the product. GCB does not guarantee the completeness of digital data stored in the product during and after warranty service, and is not liable for any damages or losses of digital data stored in repaired products. Furthermore, GCB shall, in no event, be liable for any damages to the product and/or any losses of digital data stored in the product during its delivery. Consequently, before sending the product to GCB for warranty service, if it is equipped with a storage function, it is suggested that you make a back-up of your own digital data from the product and remove it yourself therefrom.

❷ To the extent that applicable laws or regulations allow, GCB shall not be liable under any event, nor under this warranty, for any losses or profits, anticipated savings, digital data, indirect, incidental or consequential losses or damages caused by its products.

❸ GCB products are not designed with extreme precision technology or for an absolutely safety use. It is not recommended to ensemble the products onto life support machines or other emergency equipment, which may lead to personal injury or death if such equipment is defective or suffers a breakdown. Including but not limited to medical or medical-related equipment, military or military-related equipment, aircrafts, traffic control equipment, disaster prevention systems, combustion control systems, nuclear energy systems, and so forth, GCB shall not be liable for any personal injury or death, or any loss or damages to property arising from such kind of use as mentioned above.

Guarantee

• Warranty Policy

GCB warrants to the original end-user customer that its products are free from defects, in material and workmanship, on the terms and conditions set forth herein. Subject to the conditions and limitations set forth below, GCB will, at its own choice, either repair or replace any part of its products that prove defective by reason of improper workmanship or materials. Repaired parts or replacement products will be provided by GCB on an exchange basis, and will be either new or refurbished. All refurbished products have been tested to ensure that they are functionally equivalent to new products. GCB may refuse to provide inspection, repair or replacement service for products that are out of this warranty service, and will charge fees if this warranty service is exceptionally adopted.

• Warranty Period

Under normal operation, not caused by factitious damage, GCB shall provide warranty service: One-Year Warranty.

• Limited Warranty

❶ In the event that production of the specific product has been discontinued or factory repair service is no longer provided, GCB will, at its sole discretion, offer a substitute, in equivalent level or class, for such product instead. The product has a limited life-time warranty; if, under normal operation, the product is defective, this warranty service shall be applied until the product's life cycle is finished.

❷ When the damaged product is no longer under the warranty period, GCB has the right to refuse to repair or replace the product. If, eventually, GCB decides to provide the service, the customer will be charged with certain fee.

❸ After inspection, GCB has the right to determine whether to repair or to replace the product with a functionally equivalent replacement. As a result, GCB may, at its own choice, dispose of defective products. In this case, the repaired product you receive may not be the original product you sent for Warranty Service, and the original product will not be returned to you either.

GCB warrants to the original end-user customers only. On the contrary, this warranty does not apply to the products that have been sold second-hand or products not imported or sold through authorized GCB dealers or distributors. This warranty service shall not apply to transferees of GCB products and/or anyone who stands to profit from this warranty service without GCB's prior written authorization. This warranty, also, does not apply to any product on which the original identification information has been altered, obliterated or removed, or that has not been handled or packed correctly. If the product has been determined as counterfeited, this warranty is not applicable.

❶ During the warranty period, should your GCB product(s) fail, under normal use, in the recommended environment due to improper workmanship or materials, GCB is bound to provide warranty service.

❷ This limited warranty does not cover any damage to the product(s) that results from improper installation, accident, abuse, misuse, natural disaster, insufficient or excessive electrical supply, abnormal mechanical or environmental conditions, or any unauthorized disassembly, repair or modification.Including but not limited to the circumstances below:

1. GCB product failure caused by any force, major event, accident, abuse, mishandling or improper usage.
2. Any unauthorized disassembly, repair or modification.
3. The original warranty information sticker has been altered, obliterated or removed.
4. The serial number of the product is damaged, altered, unclear, torn, dirty or can't been identified.
5. The product was purchased NOT through KINGMAX authorized dealers or distributors.
6. Improper storage or environment: abnormal mechanical or environmental conditions (including prolonged exposure to humidity or extreme temperatures) can cause products to become eroded or rusted.
7. Inappropriate shipping methods or other reasons for foreseeable loss or damage.

❸ Within the warranty service period, if the product is unable to function due to a human cause (e.g. damage of the product's external appearance), the service fee must be borne by the user.The items below are included but not limited to:

1. Scratch(es) or crack(s) appearing in the printed circuit board
2. Pin scratch(es) or burns
3. Oxidized or damped pins
4. IC chip damage or fall off. (1-2 chips)
5. Severe IC chip damage or fall off (more than 3 chips): **repair service not covered**
6. Broken PCB board: **repair service not covered**
7. Revising memory module parameters without authorization of GCB, or other severe damages that affect functionality: **repair service not covered.**

1 Safety Information

① The person who uses the pulse oximeter must receive adequate training before use.
② The pulse oximeter is intended for patient assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended for treatment.
③ When using the pulse oximeter together with the electrical surgery equipment, the user should ensure safety of the testee.
④ **EXPLOSION HAZARD:** Do not use the pulse oximeter in the environment of flammable anesthetics, explosive substances, vapors or liquids.
⑤ It is forbidden to use the pulse oximeter in MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) environment because the induced current could potentially cause burning.
⑥ The pulse oximeter has no alarm function. Continuous monitoring for a long time is not suitable.
⑦ No modification of this product is allowed. Maintenance should be operated by professional maintenance personnel who are approved by manufacturers.
⑧ Please shut off the power before cleaning the pulse oximeter. It is forbidden to disinfect the pulse oximeter via high-pressure and high-temperature methods. The cleaning agents/disinfectants which are other than recommended ones in the operation manual are not allowed to use.
⑨ The product is commonly seal product. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
⑩ The pulse oximeter is precision and fragile. Avoid pressure, knock, strong vibration or other mechanical damage. Hold it carefully and lightly. If it is not in use, it should be appropriately placed.
⑪ The disposal of the pulse oximeter and accessories should follow local regulations or your hospital's policy regarding disposal of such pulse oximeter and accessories. Do not dispose randomly.
⑫ Don't dismantle and replace the battery without authorization. When the battery is low or it has not been used for a long time, please charge the battery in time but protecting against overcharging.

⑬ Please use the SpO_2 sensor which matched with the product or use the SpO_2 sensor which the manufacturer has approved of it. The operator is responsible for checking the compatibility of the pulse oximeter, sensor and cable before use. And incompatible components can result in degrading performance. If there are signs of damage, please stop using.

⑭ If testee is an intended operator, you must read the operation manual carefully and understand deeply or consult with the doctor and manufacturer before using. If you have any discomfort in use, please stop using immediately and go to the hospital.

⑮ If the accessories are intended for single-use, please scrap according to relevant regulations after use. It is forbidden to re-use.

⑯ A functional tester can't be used to assess the accuracy.

⑰ To avoid that static electricity damages the pulse oximeter, direct or indirect static electricity attached to the operators or testees should be confirmed before using.

⑱ Try to make the pulse oximeterkeeps away from radio receiver when it is in use.

⑲ If the pulse oximeter uses with configuration which does not pass EMC test, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.

⑳ Portable and mobile radio frequency communication equipment can affect the normal use of the pulse oximeter.

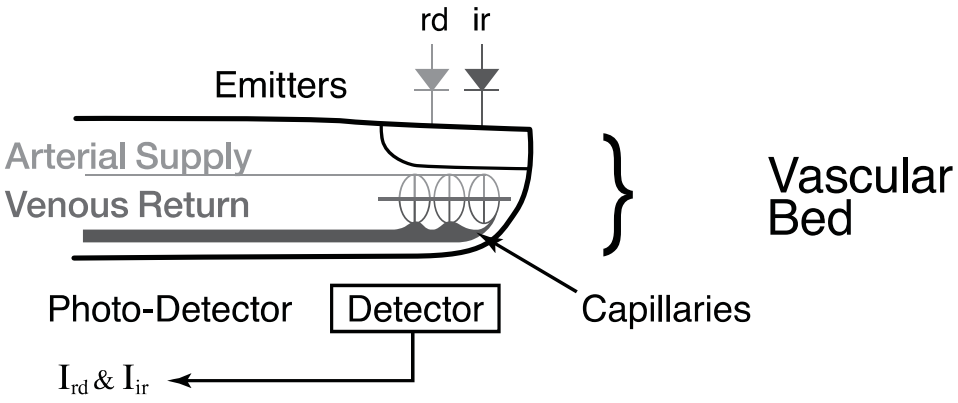
㉑ The pulse oximeter should not be close to or stacked with other devices, if they have to be close to or stacked with together in use, you should observed and verify that it can run normally with the configuration.

㉒ If the product is intended to allow direct diagnosis or monitoring of vital physiological processes, then it is likely to result in the immediate danger to the testee.

㉓ It should be ensured that there is no dirt or wound on the tested part.

㉔ Federal law restricts this device to sale by or on the order of a physician.

2 Measurement Principle



Arterial oxygen saturation is measured via a method which is called oximetry.

An experience formula of data process is established by taking use of Lambert Beer Law, and according to Spectrum Absorption Characteristics of hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow and near-infrared zones.

The operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology. Two beams of different wavelength of lights can be focused on human nail tip via emitters by adopting the Capacity Pulse Scanning and Recording Technology. Then measured signal will be obtained via a photosensitive element. The amount of light absorbed is related to the amount of oxygen in the blood during these pulses. The ratio of the two absorbed spectrums can be calculated via the microprocessor and the results are compared with the saturation valuein the memory, so the blood oxygen saturation value is obtained.

◎ The range of wavelength of light: 660~905 nm
◎ Maximum output power of light: 2.0 mW

3 Product Feature

① Simple and user friendly for operating with one button.
② Small size, light weight, convenient to carry.
③ Lower consumption, original one 3.7V lithium battery can continuously work for 12 hours.
④ The machine will automatically power off when there's no signal generated.
⑤ Daily maintenance and calibration is unnecessary.
⑥ Communication can be realized between the product and mobile phone with its wireless Bluetooth for data recording.

4 Applicable Scope

The pulse oximeter is suitable for monitoring adults and be used in clinic section office, out-patient department and sickroom generally. It also can be used in the recovery and health care organizations, and the community medical treatments.

5 Contraindications

Before operation, please must ensure there is no wound on skin tissues where need to contact with SpO_2 sensor. And recommend strongly don't use continuously at same finger site over 8 hrs for each measurement.

6 Product Composition

① PulseOximetry Body x1

② Watchband x1

Optional Item

③ Disposable sponge SpO_2 probe x1

Optional Item

④ USB charging cable x1

⑤ User Manual x1

7 Product Specifications

- **Display mode:**
  OLED

- **Body Size:**
  57mm (L)×53.6mm (H)×15.2mm(D)

- **Weight:**
  47g (Excluding Sensor and Wrist strap)

SpO_2

Measurement range:	35~100%
Accuracy:	±2% (80%~100%)
	±3% (70%~79%)

Pulse Rate

Measurement range:	25~250 bpm
Accuracy:	±2 bpm

- **Electrical specifications:**

Working voltage:	D.C. 3.4V~D.C.4.3V
Battery Type:	one 3.7V lithium battery
Power consumption:	smaller than 50mA

8 Notifications

① Don’t put the pulse oximeter on extremities with arterial catheter or venous syringe.

② The pulse oximeter is the same as other medical equipment. It should connect the cable carefully. And avoid testee is winded or suffocates. Electric surgical equipment cable can’t entwine with sensor cable.

③ Please cover the sensor with opaque material under the condition of strong light. Otherwise, it can cause inaccurate measurement.

④ Try to keep the testee still (specially the arm) and avoid the measured site suffering excessive motion.

⑤ Don’t use the pulse oximeter to measure testees whose pulse rate is lower than 30bpm, it may cause incorrect results.

⑥ The product is prone to crossed contamination when it’s used on different testees. Disinfection is recommended before using the product on other testees.

⑦ Please change sensor location and check skin integrity and circulatory status at least every 2 hours.

⑧ Don’t perform SpO_2 and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO_2 value.

⑨ Tester’s fingernail can’t be too long. Otherwise the finger can’t be inserted into the sensor to a suitable depth and the SpO_2 measurements may be inaccurate.

⑩ Make sure to place the product on the finger in a correct direction. The LED part of the sensor should be at the backside of the testee hand and photo-detector part at the inside. Make sure to insert the finger to suitable depth into the sensor so that the fingernail is just opposite to the light emitted from the sensor.

⑪ The highest temperature of sensor contacts with testee’s skin doesn’t be allowed more than 41°C.

⑫ Shock, anemia, hypothermia and the application of vasoconstriction drug may decrease arterial blood flow to an immeasurable level.

⑬ Pigment, or deep color (for example: nail polish, artificial nails, dye or pigmented cream) may cause inaccurate measurements.

⑭ **Instruction of battery charging：**

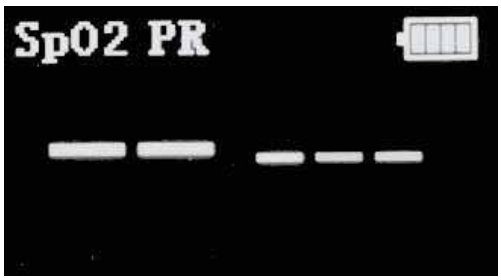
i. Connect the oximeter with the attached USB charging cable.

ii. While start charging, the battery indicator will be running as shown below.

iii. The battery indicator will stop running if the charging process is completed.

iv. Please don't use the device in an environment surrounding Electromagnetic Interference.

⑮ While unplugging the probe, device will enter standby mode as shown below.

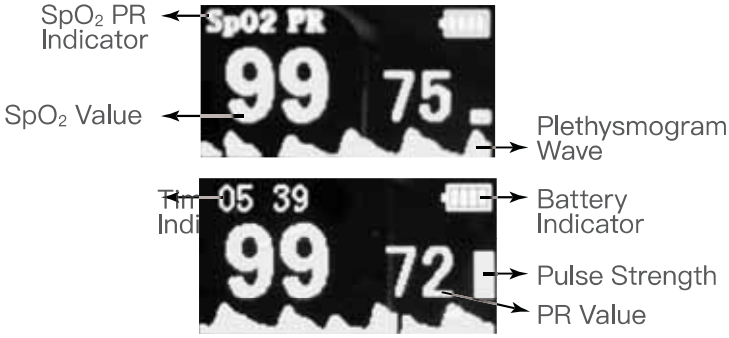


9 Directions for Measurement

① Insert the plug of the sensor into the slot of the wrist pulse oximeter.

② Open the power of the wrist pulse oximeter, monitoring interface appears on OLED display.

③ Installing the sensor on the appropriate part of the testee's body.



④ Wait few seconds, data will be shown on the screen.

⑤ Display screen data refresh time for one second. While push ON/OFF button, the OLED display will switch to time mode; push ON/OFF button again, the display will switch back to SpO_2 PR mode.

⑥ Keeping the test mode for at least 15 mins to generate a valid test record.

⑦ For power saving consideration, screen display will turn off automatically after 1 minute. Push ON/OFF button, the screen wakes up again.

⑧ Device will power off automatically after 10 minutes during standby mode.

⑨ Steady press ON/OFF button for at least 3 seconds, device will be power off instantly at any moment.

⑩ The valid test record exists and stored in device, the data can be transmitted to your personal device via Bluetooth. If you like to know how it works, please feel free to contact your dealer directly.

10 Cleaning and Disinfection

- **Cleaning:**

① Clean the product with cotton or soft cloth moistened with water.
② After cleaning, wipe off the water with a soft cloth.
③ Leave the device to dry naturally.

- **Disinfection:**

The recommended disinfectants include: 70% ethanol, 70% isopropanol, glutaraldehyde (2%) solution disinfectants.

① Clean the product as instructed above.
② Disinfect the product with cotton or soft cloth moistened with one of the recommended disinfectants.
③ After disinfection, be sure to wipe off the disinfectant left on the product with a soft cloth moistened with water.
④ Leave the device to dry naturally.

11 Environment Requirements

- **Temperature:**

Operation: +5~+35°C
Transportation and storage: -10~+50°C

- **Atmospheric pressure:**

Operation: 860hPa~1060hPa
Transportation and storage: 700hPa~1060hPa

- **Humidity:**

Operation: 15%~80% (noncondensing)
Transportation and storage: 10%~90% (noncondensing)

- **note:**

A functional tester can't be used to evaluate the accuracy.
The method of confirming the blood oxygen measurement accuracy is to compare the oximetry measurement value with the value of blood gas analyzer.

12 Troubleshooting

❓ The SpO_2 and PR cannot be displayed normally and the value disappeared.

① The finger is not properly positioned; please try again.
② The testee's SpO_2 is too low to be detected; Please try again or go to a hospital for a diagnosis if you are sure the device works normally.
③ The plug of sensor falls off; please insert the plug of sensor tightly as far as possible.

❓ The SpO_2 and PR display unstable.

① The finger is not placed inside enough; please place the finger properly and try again.
② The finger is shaking or the user is moving; keep the user calm and steady.

❓ The device can't be powered on.

① The batteries are drained or almost drained; please charge the batteries.
② The device is malfunctioned; please contact the vendor.

❓ The screen is suddenly off.

① The product is automatically powered off when no signal is detected longer than 10 minutes; normal.
② Power of the batteries is exhausted; please charge the batteries.

13 Description of Symbols

SN Serial Number	Bluetooth
Please refer to the operation manual.	Attention, see Manual instruction for use.
Recycle	The product does not contain alarm function.
Direct Current	Information of manufacture
Type **BF** equipment	IP22 Degrees of protection provided by enclosure

"Not for general waste." When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.

14 Disposal

Dispose of the oximeter in accordance with local environment and waste disposal laws and regulations.

Declaration of Conformity

For IEC 60601-1-2 (3rd Ed.)

Company Name: Taiwan Green Cross Co., Ltd.

Company Address: 6F., No. 244, Sec. 3, Chengteh Road, Taipei, 10367, Taiwan, R.O.C.

Trade Name: GCB

Report Number: 20-02-RBO-025

Power Supply: Battery Pack: 3.7V, 720mAh

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The GCB Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GCB Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GCB Pulse Oximeter 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 $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.67	11.67	23.33

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are LIFE-SUPPORTING

The GCB Pulse Oximeter declaration – electromagnetic immunity

The GCB Pulse Oximeter system is intended for use in the electromagnetic environment specified below.
The customer or the user of the GCB Pulse Oximeter system should assure that it 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 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m ; 10 V/m 80 MHz to 2.5 GHz	10 V/m	

Declaration – electromagnetic immunity

The GCB Pulse Oximeter system is intended for use in the electromagnetic environment specified below.
The customer or the user of the GCB Pulse Oximeter system 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic emissions

The GCB Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the GCB Pulse Oximeter should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The GCB Pulse Oximeter 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 GCB Pulse Oximeter 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	N/A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	N/A	

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

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.

IMPORTANT NOTE:
Radiation Exposure Statement:
The product comply with the US portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

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

GCB Pulse Oximeter

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