Test Solutions **for**
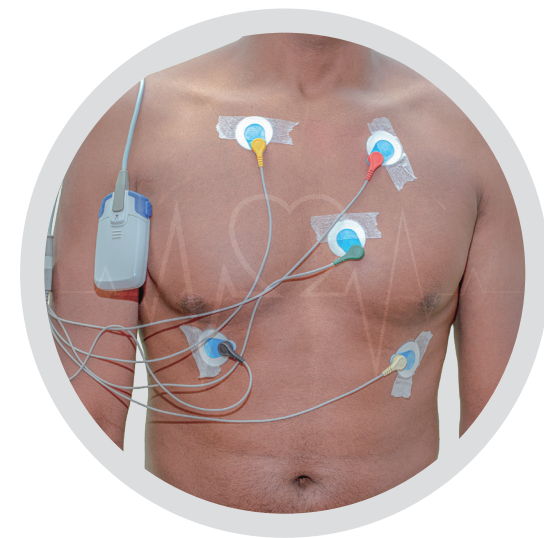Medical Device Manufacturers
WHALETEQ

安心合規

IEC 60601-2-47
標準測試完整方案

僅須依操作步驟點擊，即可完成所有必要的動態心電圖性能和數據庫測試，節省研究醫療標準和培訓的時間。

模擬器與測試儀器

Ⓐ **SECG 5.0 AIO** 多生理訊號模擬器，包含 IEC 60601-2-47 輔助軟體

Ⓑ **MECG 2.0** ECG 數據庫播放器

Ⓒ **CMRR 3.0+** 共模抑制比測試儀，包含 IEC 60601-2-47 輔助軟體

方案內容

ECG 醫療數據庫比對軟體
❶ RDCA（節律診斷用數據庫合規分析儀）6 個月訂閱制

ECG 醫療數據庫
❷ AHA 數據庫

配件
❸ 降噪金屬板 x 1
❹ 複合式端子頭 x 35
❺ 接地線 x 3
● RCA 對 BNC 接線 x 1
● USB 接線 x 2
● 屏蔽盒 x 1
● USB 隔離器 x 1

培訓與服務
● 模擬器與測試儀器 基本操作培訓 3 小時
● IEC 60601-2-47 測試標準培訓 2 小時
● 測試專業諮詢 2 小時

選配項目 ● C3R3 3 年校驗服務及延伸保固

Ⓐ SECG 5.0 AIO 測試設置圖 – 驗證 ECG 硬體設計

這款單機操作的心電圖模擬器提供靈活的參數設置，包括雜訊、呼吸和導聯脫落模擬，以及內建 IEC 60601-2-47 標準輔助軟體。
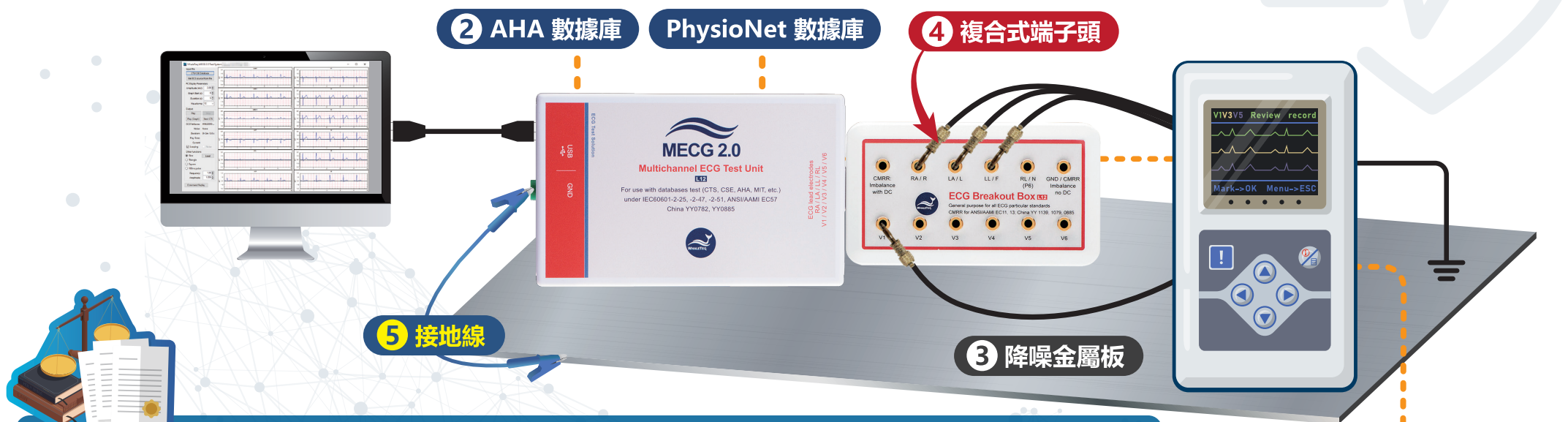

❹ 複合式端子頭

❺ 接地線

❸ 降噪金屬板

支援 IEC 60601-2-47 標準測試項目

- 201.12.1.101.2.3.3.2 Heart rate variability or RR interval variability test patterns
- 201.12.4.4.101 Linearity and dynamic range
- 201.12.4.4.102 Input impedance
- 201.12.4.4.104 GAIN accuracy
- 201.12.4.4.105 GAIN stability
- 201.12.4.4.107 Multichannel crosstalk
- 201.12.4.4.108 Frequency response
- 201.12.4.4.109 Function in the presence of pacemaker pulses
- 201.12.4.4.110 Timing accuracy
- 201.12.4.4.111 GAIN settings and switching
- 201.12.4.4.112 Temporal alignment
- 201.15.4.3.101.1 Monitoring time

Ⓑ MECG 2.0 測試設置圖 – 驗證 ECG 演算法設計

心電圖數據庫播放器將原始數據轉換為類比信號，以驗證心電圖演算法。

② AHA 數據庫　PhysioNet 數據庫　④ 複合式端子頭

MECG 2.0
Multichannel ECG Test Unit
For use with databases test (CTS, CSE, AHA, MIT, etc.)
under IEC60601-2-25, -2-47, -2-51, ANSI/AAMI EC57
China YY0782, YY0885

ECG Breakout Box
General purpose for all ECG particular standards
CMRR for ANSI/AAMI EC11, 13. China YY 1139, 1079, 0885

CMRR Imbalance with DC　RA / R　LA / L　LL / F　RL / N (P6)　GND / CMRR Imbalance no DC
V1　V2　V3　V4　V5　V6

V1V3V5　Review record
Mark→OK　Menu→ESC

⑤ 接地線

③ 降噪金屬板

支援 IEC 60601-2-47 標準測試項目
MECG 2.0 & RDCA

- 201.12.1.101.1.2.1 The accuracy of QRS detection
- 201.12.1.101.1.2.2 The accuracy of heart rate measurements
- 201.12.1.101.1.2.3 The accuracy of VEB detection
- 201.12.1.101.1.2.4 Claimed to detect ventricular flutter or fibrillation (VF)
- 201.12.1.101.1.2.5 Claimed to detect supraventricular ectopic beats, or atrial flutter or fibrillation (AF), claimed to measure ST SEGMENT deviations or to detect ST SEGMENT changes
- 201.12.1.101.1.5.1 Required statistics
- 201.12.1.101.1.5.2 Requirements for all arrhythmia algorithms
- 201.12.1.101.1.5.3 Requirements for algorithms with optional capabilities
- 201.12.1.101.1.6 Simulated test patterns
- 201.12.1.101.2.1 Use of standard databases
- 201.12.1.101.2.2 Use of annotation files
- 201.12.1.101.2.3 Beat-by-beat comparison
- 201.12.1.101.2.3.1 General description
- 201.12.1.101.2.3.2 Method for beat-by-beat comparison

- 201.12.1.101.2.3.3.1 Heart rate measurement
- 201.12.1.101.2.4 Run-by-run comparison
- 201.12.1.101.2.4.1 General description
- 201.12.1.101.2.4.2 Terms and symbols
- 201.12.1.101.2.4.3 Run sensitivity summary matrix
- 201.12.1.101.2.4.4 Run positive predictivity summary matrix
- 201.12.1.101.2.5 VF and AF comparisons
- 201.12.1.101.3 Physician report – minimum requirements
- 201.12.1.101.3.1 Heart rate
- 201.12.1.101.3.2 Supraventricular ectopy
- 201.12.1.101.3.3 Ventricular ectopy
- 201.12.1.101.3.4 Bradycardia data
- 201.12.1.101.3.5 PAUSES
- ◎ 201.12.1.101.3.6 ST SEGMENT shifts *
- 201.12.1.101.3.7 ECG hard copy

* 備註：RDCA 僅適用於此測項的部分項目。

測試註釋檔

① RDCA
數據庫比對軟體
該軟體分析測試結果並使用內建的參考值來改進演算法。

測試報告

Ⓒ CMRR3.0+ 測試設置圖 – 驗證 ECG 共模抑制比

這款測試儀器能減輕主電源頻率噪音的干擾，同時幫助省下設置無噪音測試環境的時間。

④ 複合式端子頭

⑤ 接地線

V1V3V5 Review record

Mark->OK Menu->ESC

③ 降噪金屬板

Standard
IEC-2-25
Supply Voltage
20.00 Vrms
Frequency
60 Hz
Inner Shield(Vc)
11.46 Vrms
Electrode with Impedance
NONE
DC Offset
OFF

Adjustable Capacitor
Coarse

Adjustable Capacitor
Fine

WHALETEQ
CMRR 3.0+
ECG & EEG CMRR Tester

支援 IEC 60601-2-47 標準測試項目
- 201.12.4.4.103 Common mode rejection
- 201.12.4.4.106 System noise

IEC 60601-2-47

測試項目	SECG 5.0 AIO	MECG 2.0	CMRR 3.0+	RDCA
201.12.1.101.1.2.1 The accuracy of QRS detection		●		●
201.12.1.101.1.2.2 The accuracy of heart rate measurements		●		●
201.12.1.101.1.2.3 The accuracy of VEB detection		●		●
201.12.1.101.1.2.4 Claimed to detect ventricular flutter or fibrillation (VF)		●		●
201.12.1.101.1.2.5 Claimed to detect supraventricular ectopic beats, or atrial flutter or fibrillation (AF), claimed to measure ST SEGMENT deviations or to detect ST SEGMENT changes		●		●
201.12.1.101.1.5.1 Required statistics		●		●
201.12.1.101.1.5.2 Requirements for all arrhythmia algorithms		●		●
201.12.1.101.1.5.3 Requirements for algorithms with optional capabilities		●		●
201.12.1.101.1.6 Simulated test patterns		●		●
201.12.1.101.2.1 Use of standard databases		●		●
201.12.1.101.2.2 Use of annotation files		●		●
201.12.1.101.2.3 Beat-by-beat comparison		●		●
201.12.1.101.2.3.1 General description		●		●
201.12.1.101.2.3.2 Method for beat-by-beat comparison		●		●
201.12.1.101.2.3.3.1 Heart rate measurement		●		●
201.12.1.101.2.4 Run-by-run comparison		●		●
201.12.1.101.2.4.1 General description		●		●
201.12.1.101.2.4.2 Terms and symbols		●		●
201.12.1.101.2.4.3 Run sensitivity summary matrix		●		●
201.12.1.101.2.4.4 Run positive predictivity summary matrix		●		●
201.12.1.101.2.5 VF and AF comparisons		●		●
201.12.1.101.3 Physician report – minimum requirements		●		●
201.12.1.101.3.1 Heart rate		●		●
201.12.1.101.3.2 Supraventricular ectopy		●		●
201.12.1.101.3.3 Ventricular ectopy		●		●
201.12.1.101.3.4 Bradycardia data		●		●
201.12.1.101.3.5 PAUSES		●		●
201.12.1.101.3.6 ST SEGMENT shifts		●		◎
201.12.1.101.3.7 ECG hard copy		●		●
201.12.1.101.2.3.3.2 Heart rate variability or RR interval variability test patterns	●			
201.12.4.4.101 Linearity and dynamic range	●			
201.12.4.4.102 Input impedance	●			
201.12.4.4.103 Common mode rejection			●	
201.12.4.4.104 GAIN accuracy	●			
201.12.4.4.105 GAIN stability	●			
201.12.4.4.106 System noise			●	
201.12.4.4.107 Multichannel crosstalk	●			
201.12.4.4.108 Frequency response	●			
201.12.4.4.109 Function in the presence of pacemaker pulses	●			
201.12.4.4.110 Timing accuracy	●			
201.12.4.4.111 GAIN settings and switching	●			
201.12.4.4.112 Temporal alignment	●			
201.15.4.3.101.1 Monitoring time	●			

● 適用　　◎ 部分適用