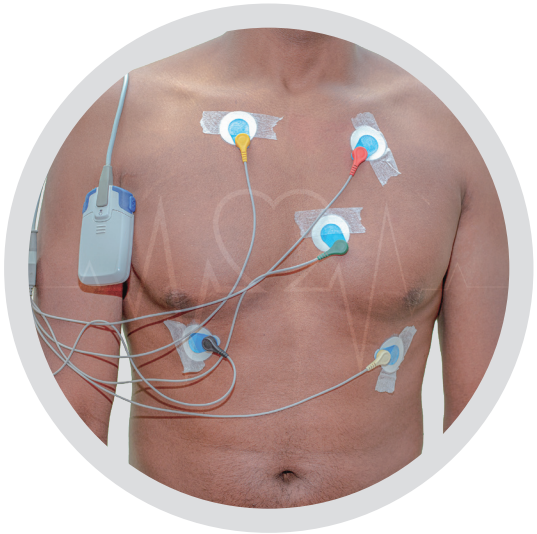
WHALETEQ Test Solutions for Medical Device Manufacturers



安心合规

IEC 60601-2-47 标准测试完整方案

仅须依操作步骤点击，即可完成所有必要的动态心电图性能和数据库测试，节省研究医疗标准和培训的时间。

方案内容

模拟器与测试仪器

- Ⓐ **SECG 5.0 AIO** 多生理信号模拟器，包含 IEC 60601-2-47 辅助软件
- Ⓑ **MECG 2.0** ECG 数据库播放器
- Ⓒ **CMRR 3.0+** 共模抑制比测试仪，包含 IEC 60601-2-47 辅助软件

ECG 医疗数据库比对软件

1. RDCA（节律诊断用数据库合规分析仪）6 个月订阅制

ECG 医疗数据库

2. AHA 数据库

配件

3. 降噪金属板 x 1
4. 复合式端子头 x 35
5. 接地线 x 3
- RCA 对 BNC 接线 x 1
- USB 接线 x 2
- 屏蔽盒 x 1
- USB 隔离器 x 1

培训与服务

- 模拟器与测试仪器 基本操作培训 3 小时
- IEC 60601-2-47 测试标准培训 2 小时
- 测试专业咨询 2 小时

选配项目

- C3R3 3 年校验服务及延伸保固

Ⓐ SECG 5.0 AIO 测试设置图 – 验证 ECG 硬件设计

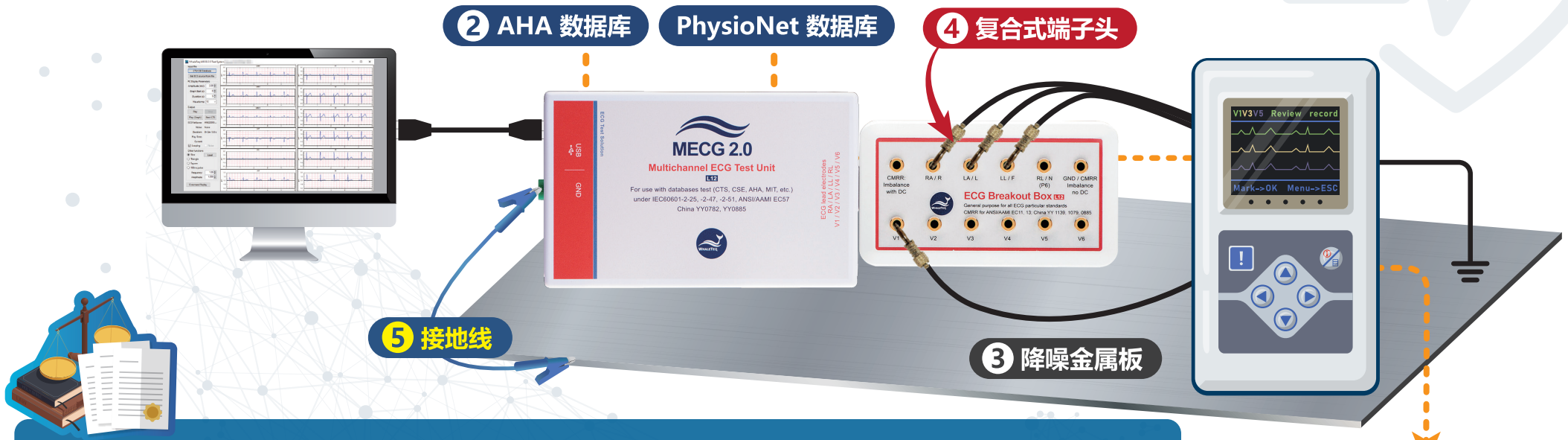
这款单机操作的心电图模拟器提供灵活的参数设置，包括噪声、呼吸和导联脱落模拟，以及内建 IEC 60601-2-47 标准辅助软件。

支持 IEC 60601-2-47 标准测试项目

- 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 测试设置图 – 验证 ECG 算法设计

心电图数据库播放器将原始数据转换为类比信号，以验证心电图算法。



支持 IEC 60601-2-47 标准测试项目

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

* 备注： RDCA 仅适用於此测项的部分项目。

测试注释档

1 RDCA
数据库比对软件
该软件分析测试结果并使用内建的参考值来改进算法。

测试报告

Ⓒ CMRR3.0+ 测试设置图 – 验证 ECG 共模抑制比

这款测试仪器能减轻主电源频率噪声的干扰，同时帮助省下设置无噪声测试环境的时间。

支持 IEC 60601-2-47 标准测试项目

- 201.12.4.4.103 Common mode rejection
- 201.12.4.4.106 System noise

IEC 60601-2-47

测试项目	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	●			

● 适用　◎ 部分适用