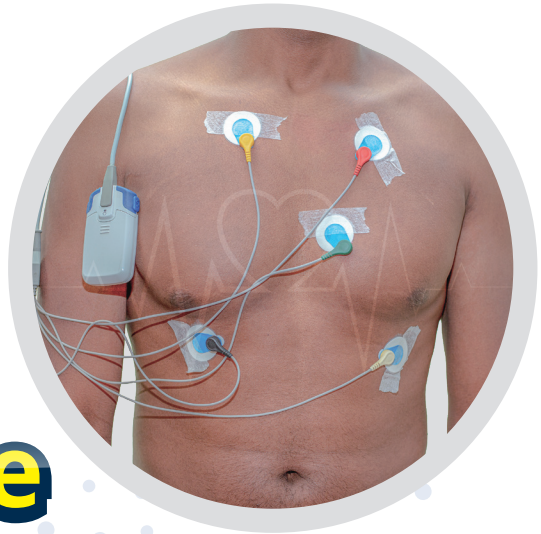
WHALETEQ Test Solutions for Medical Device Manufacturers



Trouble-Free Compliance

Comprehensive IEC 60601-2-47 Testing Package

Save time studying the medical standard and training by completing all required Ambulatory ECG performance and database testing with just a few clicks.

Package Contents

Simulator & Tester

- (A) **SECG 5.0 AIO** Multi Vital Sign Simulator includes IEC 60601-2-47 Assistant Software
- (B) **MECG 2.0** ECG Database Player
- (C) **CMRR 3.0+** Common Mode Rejection Ratio Tester includes IEC 60601-2-47 Assistant Software

ECG Medical Database Comparison Software

(1) RDCA (Rhythm Database Compliance Analyzer) (6 month subscription)

ECG Medical Database

(2) AHA Database

Accessories

(3) Compound Terminal x 35
(4) Grounding Wire x 3
- RCA to BNC Cable x 1
- USB Cable x 2
- Shielding Box x 1
- USB Isolator x 1

Training & Service

- Simulator & Tester Operation Training (3 hours)
- IEC 60601-2-47 Testing Training (2 hours)
- Testing Consultation (2 hours)

Optional Items
- C3R3 3-Year Calibration Service and Warranty Extension

Ⓐ SECG 5.0 AIO Installation – ECG Hardware Design Verification

The standalone ECG simulator offers flexible parameter settings, including noise, respiration, and lead-off simulation, as well as embedded IEC 60601-2-47 standard assistant software.

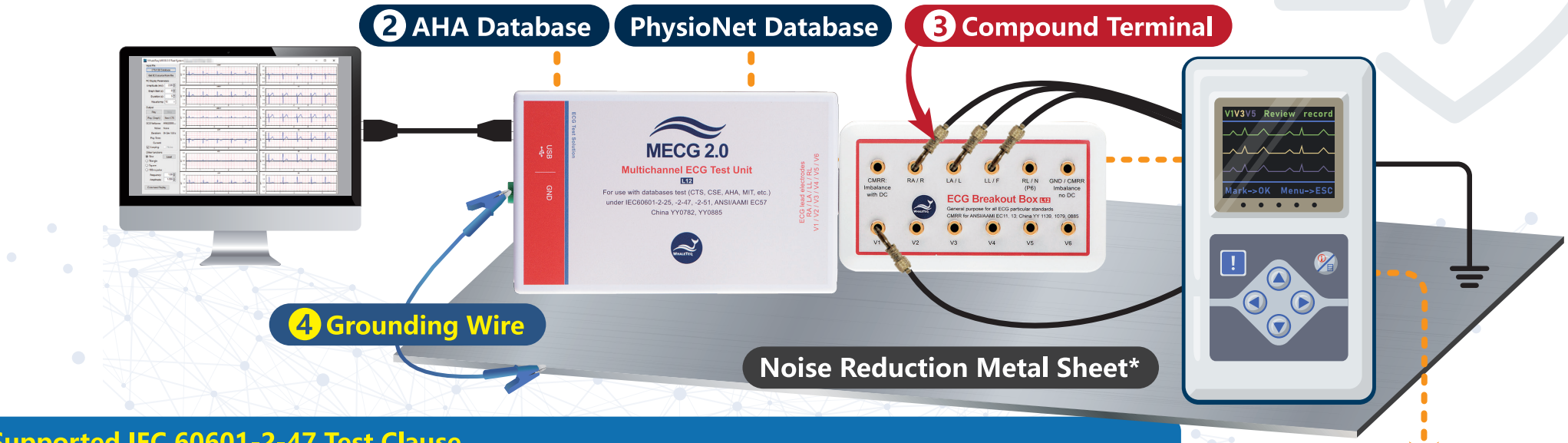
Supported IEC 60601-2-47 Test Clause

- 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

*Recommended Metal Sheet Specifications:
[Material] Aluminum, steel, or copper are acceptable; copper is recommended for optimal performance.
[Dimensions] The thickness is not specified, but a recommended size is 60cm × 100cm. A larger surface area provides better noise reduction.
The metal sheet itself serves as a standalone ground and must not be connected to any other grounding point.

Ⓑ MECG 2.0 Installation – ECG Algorithm Design Verification

The ECG database player converts raw data into analog signals to verify ECG interpretation algorithms.



Supported IEC 60601-2-47 Test Clause

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

*Note: The RDCA is partially applicable to this test clause.

Test Annotation File

1 RDCA
Database Comparison Software
The software analyzes test results with built-in reference values to improve algorithms

Statistic Report

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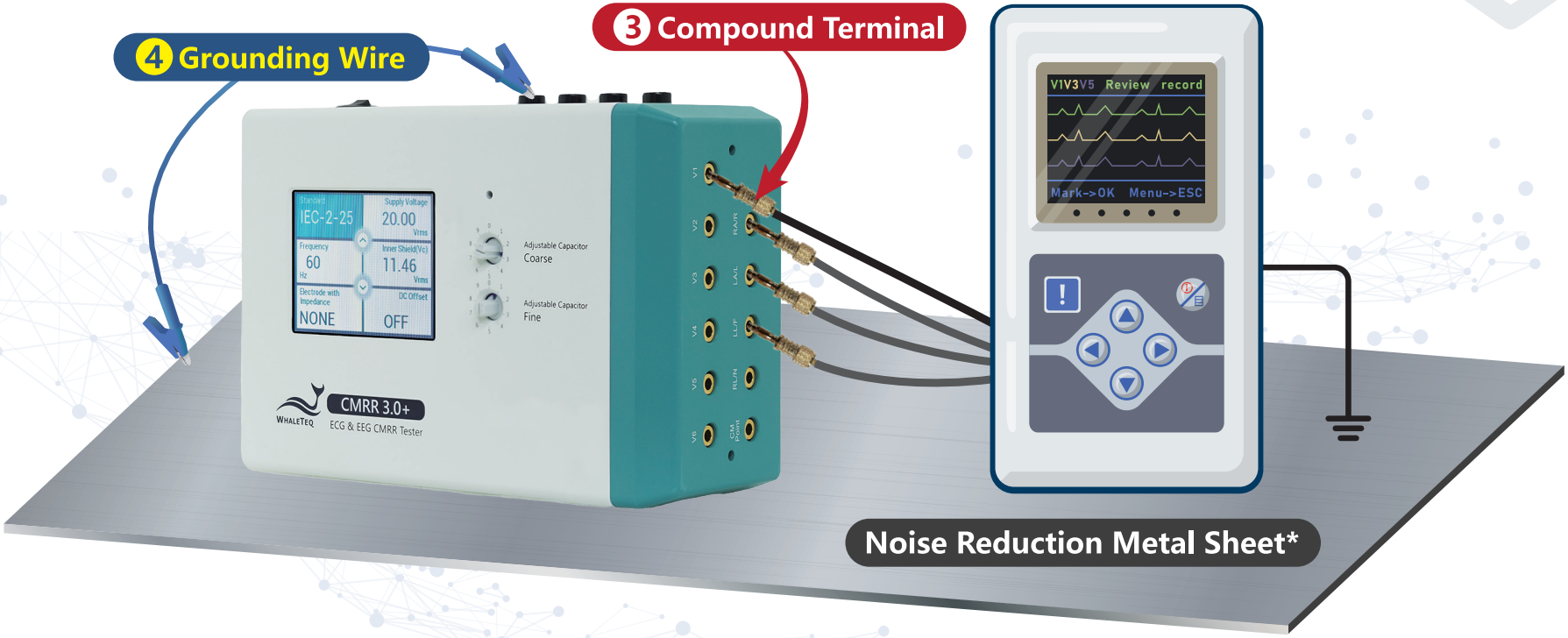
© CMRR 3.0+ Installation – ECG Common Mode Rejection Ratio Verification

The tester mitigates mains frequency noise interference while helping save time on setting up a noise-free test environment.



Supported IEC 60601-2-47 Test Clause

- 201.12.4.4.103 Common mode rejection
- 201.12.4.4.106 System noise

*Recommended Metal Sheet Specifications:
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[Dimensions] The thickness is not specified, but a recommended size is 60cm × 100cm. A larger surface area provides better noise reduction.
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IEC 60601-2-47

● Applicable ◎ Partially Applicable

Test Clause	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	●			