**Test Solutions** for
Medical Device Manufacturers

**WHALETEQ**

**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 | ECG Medical Database | Accessories | Training & Service |
|---|---|---|---|
| **(1)** RDCA (Rhythm Database Compliance Analyzer) (6 month subscription) | **(2)** AHA Database | **(3)** Noise Reduction Metal Plate x 1 <br> **(4)** Compound Terminal x 35 <br> **(5)** Grounding Wire x 3 <br> • RCA to BNC Cable x 1 <br> • USB Cable x 2 <br> • Shielding Box x 1 <br> • USB Isolator x 1 | • Simulator & Tester Operation Training (3 hours) <br> • IEC 60601-2-47 Testing Training (2 hours) <br> • 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.
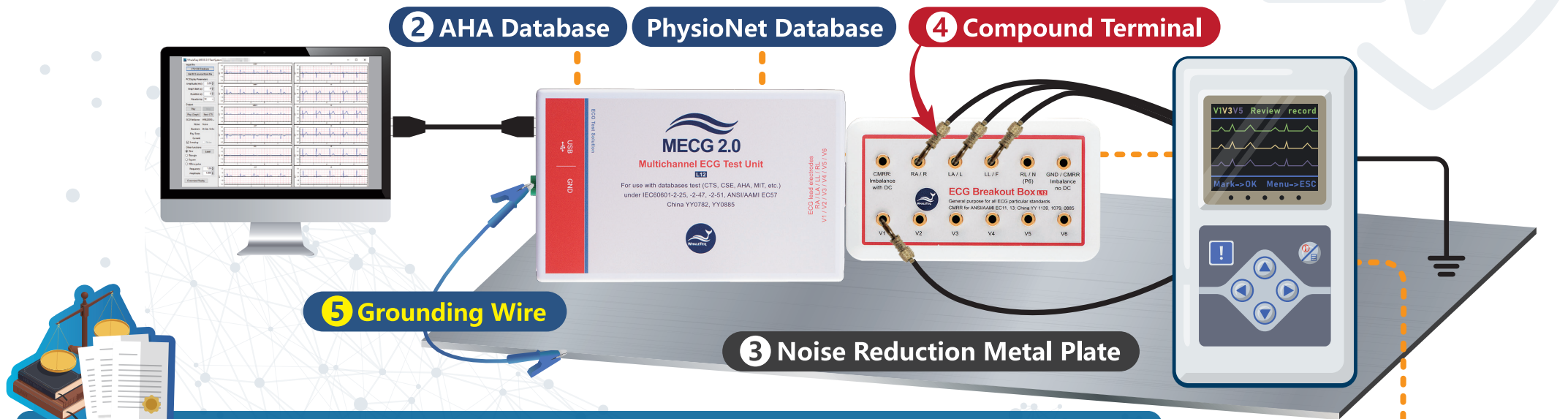
**❹ Compound Terminal**

**❺ Grounding Wire**

**❸ Noise Reduction Metal Plate**
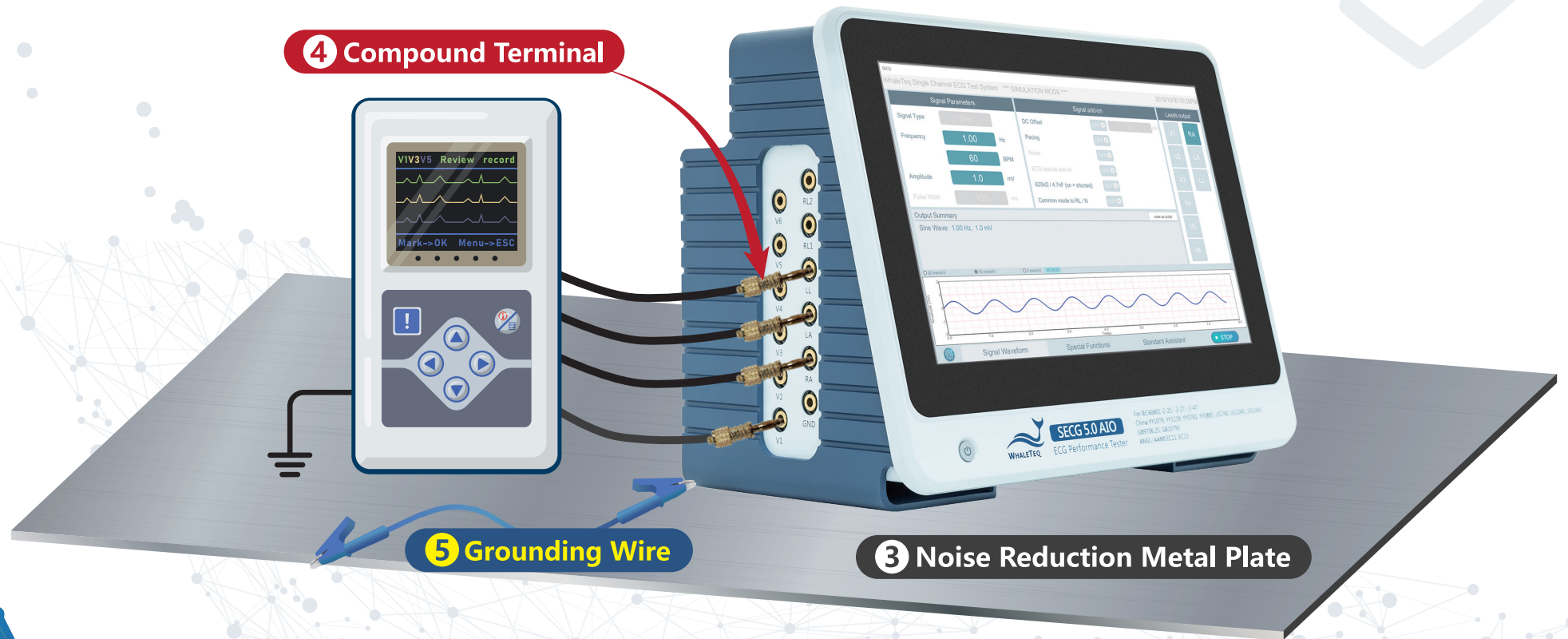
**Supported IEC 60601-2-47 Test Clause**
- 201.12.1.101.2.3.3.2 Heart rate variability or RR interval variability test patterns
- 201.12.4.4.101 Linearity and dynamic range
- 201.12.4.4.102 Input impedance
- 201.12.4.4.104 GAIN accuracy
- 201.12.4.4.105 GAIN stability
- 201.12.4.4.107 Multichannel crosstalk
- 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

# Ⓑ MECG 2.0 Installation – ECG Algorithm Design Verification

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

**❷ AHA Database**  **PhysioNet Database**  **❹ Compound Terminal**

**MECG 2.0**
Multichannel ECG Test Unit
**L12**
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 lead electrodes
RA / LA / LL / RL
V1 / V2 / V3 / V4 / V5 / V6

USB

GND

**ECG Breakout Box** L12
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

**❺ Grounding Wire**

**❸ Noise Reduction Metal Plate**

## 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

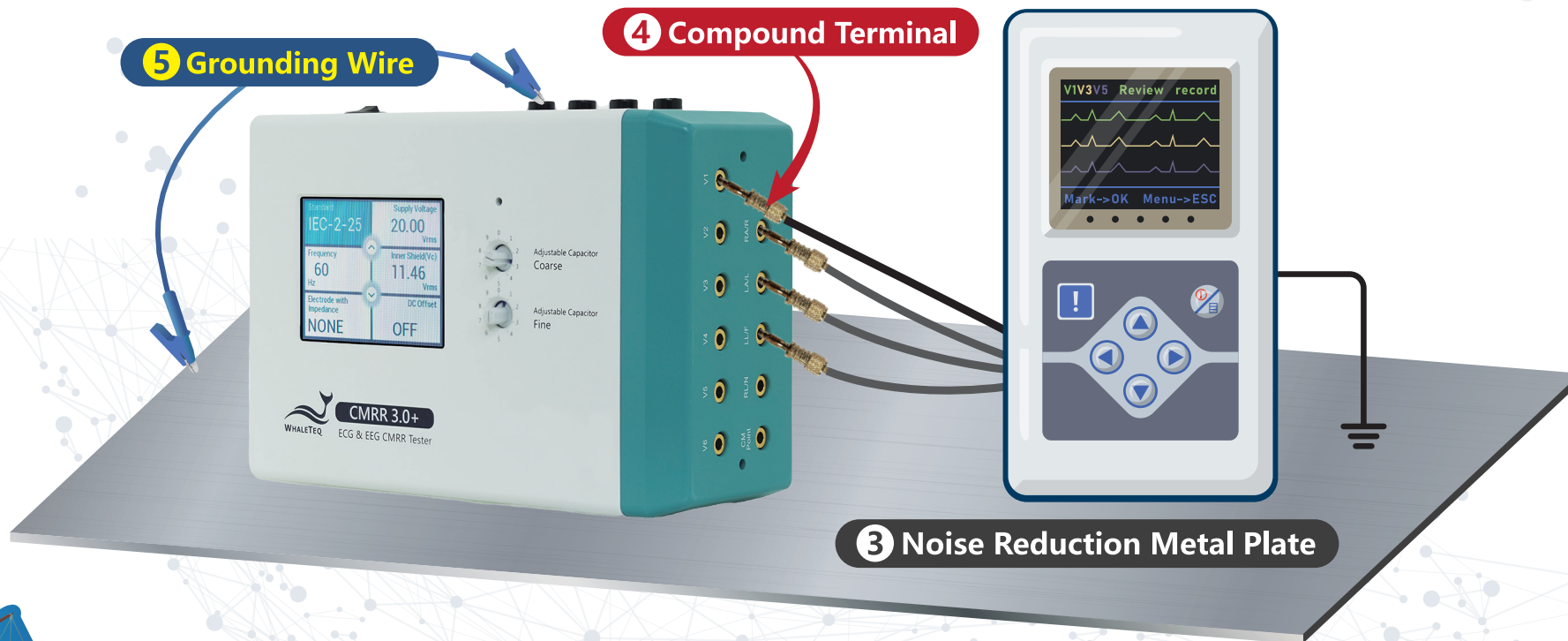*Note: The RDCA is partially applicable to this test clause.

**Test Annotation File**

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

**Statistic Report**

# C 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.**



**5 Grounding Wire**

**4 Compound Terminal**

**3 Noise Reduction Metal Plate**

CMRR 3.0+
ECG & EEG CMRR Tester

**Supported IEC 60601-2-47 Test Clause**
- 201.12.4.4.103 Common mode rejection
- 201.12.4.4.106 System noise

# IEC 60601-2-47

| 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 | ● | | | |

● Applicable    ◎ Partially Applicable