USES:

- IEC 60601-1 Testing
- Endoscope, Light Source Testing
- Testing Mains Powered & Internally Powered Devices
- Testing Medical Devices with B-Type Applied Parts

TEST CAPABILITY:

- Ground Bond
- AC Hipot up to 5kVac
- DC Hipot up to 6kVdc
- Patient Leakage
- Earth Line Leakage
- Enclosure Leakage
- Patient Auxiliary Leakage
- Programmable AC Source

ATE HARDWARE:

- Guardian 6100Plus Safety Analyzer
- AC Source (1500VA or 800VA)
- (1) G32 1000VA Isolation Transformer
- (1) G42 Barcode Scanner
- (2) RS-232 Cables
- (2) USB RS-232 Adapters
- Cables and adapters for DUT connections

SOFTWARE:

CaptivATE

Medical Systems Sentinel II

Introduction

The Sentinel II System provides complete Electrical Safety Testing to IEC60601-1 in a fully automated fashion. Sentinel II saves time by scanning patient connections for leakage current without powering down the medical device. The Sentinel II System can be configured to accommodate Class I, Class II, Mains and Internally Powered medical devices with the following configurations:

- Mains Power supply up to 1500VA, 0~300Vac @ 15~1kHz
- Up to 1 B-Type Patient Connection

Description

Engage Medical Device Functions: Use the Sentinell II System to create 'worst case' leakage current conditions before making measurements. Allows PC systems to power up prior to making the leakage current measurement.

AC Source: Automatically program and regulate mains voltage and frequency applied to the device under test.

CaptivATE Software: Create test sequences, capture data, provide bar code scanning of device model and serial number, automatic recall of test setup based upon model number and all data is saved into a database for trending and analysis.

CaptivATE software eliminates the need for the operator to make Pass/Fail judgment, record test results, make process deviation decisions, selection of the proper test, and interface with multiple types of test equipment

The Sentinel II System Testing Capability: Using CaptivATE software, an AC Source and a G6100 Plus Series Analyzer, possible test functions include AC or DC Hipot, insulation resistance, ground bond, earth leakage, patient leakage, patient auxiliary leakage or enclosure current leakage, as well as a functional run test. The Guardian 6100 Plus has an internal leakage current scanner with 20A input current capability.





For more detailed information on specifications, pricing and special purchase, rent and lease options, contact us

www.quadtech.com



Hipot Testers • LCR Meters • Cable Testers • AC/DC Programmable Power Sources • Megohmmeters • Milliohmmeters

Sentinel II System

IEC 60601-1Testing

with 1500VA AC Source and 1Patient Connection

G6100 Plus Captivate Software 61603 1500VA AC Source

Sentinel IIa System

IEC 60601-1Testing

with 800VA AC Source and 1Patient Connection

G6100 Plus CaptivateSoftware 6408-1 800VA AC Source

Guardian 6100 Plus:

- · Programmable AC Hipot Voltage 50 to 5000VAC, Output Current to 40mA
- Programmable DC Hipot Voltage 50 to 6000VDC, Output Current to 12mA
- IR Measurements from 100kohm to 50Gohm, Test Voltage 50 to 1000VDC
- Programmable Ground Bond Current from 1 to 40A*, Resistance Measurement to 510mohms
- Twin Port Simultaneous Hipot and Ground Bond
- · Built-in 20A Hipot/Line Leakage Scanner
- Functional Run Testing: Voltage (to 300V), Current (to 20A) or Power (to 4400VA)
- Earth, Enclosure, Patient & Patient Auxiliary Leakage **Current Measurements**
- · Open/Short Circuit Detection to ensure Device Under Test is connected
- · Pause Mode Allows the Operator to Change Device Connection and Continue
- · Programmable Hi/Lo Limits for Pass/Fail Testing
- Programmable Ramp, Dwell and Test Times
- · Perform Multiple Tests in Sequence with Store/Recall of 100 Setups, 50 Steps Each
- · Front Panel Lockout Prevents Changes to Test Setup
- Automatic Offset to Zero Out Residual Current
- Fast High Voltage Cutoff and Quick Discharge of **Device Under Test**
- · RS-232 and I/O Interfaces Included Standard
- · IEEE-488 and Printer Interfaces Optional
- · Front and Rear Panel Output Connections
- · 40A Ground Bond Testing with Optional Transformer
- · GB: Standard 30A output, Optional 40A output

CaptivATE Automation Software

- Out of the Box Solution to Simplifying Electrical Safety
- Easy to use Interface for Operators
- Barcode Scan Product, Test, Print and Save Data Seamlessly
- Helps Reduce Operator Errors
- Controls Quality Records
- Central Database for all Test Data and Test Programs
- Password Verification
- 3 Levels of User Access
- For Security, Automatically Logs Off Operator if Idle
- CSV and XML Outputs Simplifies Integration to MES
- Eliminates Handwritten Data
- Outputs Data directly to Microsoft Excel for SPC and Trending
- Assists in 21CFR Part 11 Compliance
- Software is validated based upon FDA's Guidance on Principles of Software Validation
- Developed based upon QuadTech's documented SDLC **Process**
- IQOQ Test Protocol Document is Available
- Based upon years of Input and Requirements from Leading Medical Device Manufacturers

AC Sources:

- 61603 Output: 1500VA, 0-300V, 15-1kHz
- 61603 Input: 90-250V, 22A max
- 6408-1 Output: 800VA, 0-300V, 45-500Hz
- 6408-1 Input: 90-132V, 12A max
- 61604 Output: 2000VA, 0-300V, 15-1kHz
- 61604 Input: 90-250V, 28A max
- 80% Typical Efficiency
- UVP, OVP, OCP, OPP, OTP & Short Protection
- **Built in Power Factor Converter**
- AC & DC Output Voltage Mode
- 9 Measurement Parameters: V, Irms, Ipeak, lin rush, P, Q, S, PF, CF
- Programmable Voltage & Current Limits
- Store & Recall up to 9 Voltages & Frequencies
- ON/OFF Phase Angle Control
- Programmable Slew Rate (61603)
- High Output Current Crest Factor for Inrush Current Test

Ordering Information

Sentinel II System Medical Device Electrical Safety Test System

Sentinel II System

Guardian 6100 Plus Safety Analyzer 1500VA programmable AC Source

Sentinel IIa System

Guardian 6100 Plus Safety Analyzer 800VA programmable AC Source

Includes: G32 Isolation Transformer G42 Barcode Scanner RS-232 Cables USB - RS-232 Adapters Cables, Adapters reg'd for DUT

5000-04 External Scanner: 8HV, 4GB Channels 19" Rack Mount Enclosure PC, Monitor & Keyboard

For more detailed information on specifications, pricing and special purchase, rent and lease options, contact us at:

