

# Medical Systems Sentinel I

## 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
- Insulation Resistance
- Patient Leakage
- Earth Line Leakage
- Enclosure Leakage
- Patient Auxiliary Leakage

## ATE HARDWARE:

- Guardian 6100 Plus Safety Analyzer
- G42 Barcode Scanner
- RS-232 Cable
- USB - RS-232 Adapter
- Cables and adapters for DUT connections

## SOFTWARE:

- CaptivATE

## Introduction

The Sentinel I System provides fully automated Electrical Safety Testing to IEC60601-1. This system is ideal for testing medical products with one or no patient connections or low volume production where operators can manually change leads between different patient connections. The Sentinel I System accommodates Class I, Class II and internally powered medical devices with the following specifications:

- Mains Power up to 4400VA, 0~300Vac
- 1 B-Type Patient Connection

## Description

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

**Reduce Operator Interaction:** CaptivATE software eliminates the need for the operator to make Pass/Fail judgment, record test results, make process deviation decisions, select the proper test, and the need to interface with multiple types of test equipment.

**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.

**The Sentinel I System Testing Capability:** Using CaptivATE software and a QuadTech 6100 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.

**Central Database & Historical Search Capability:** Information updated in real time makes electronic record searches easier allowing for faster analysis of data for Corrective & Preventative Action and Statistical Process Control.



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

[www.quadtech.com](http://www.quadtech.com)

800-253-1230

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

## Sentinel I System

IEC 60601-1 Testing with G6100 Plus Safety Analyzer

- G6100 Plus
- Captivate Software
- (1) G32 Isolation Transformer
- (1) G42 Barcode Scanner
- (1) RS-232 Cable
- (1) USB - RS-232 Adapter
- Cables, Adapters req'd for DUT

## 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 the 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
- Built-In Operator Prompted Software Calibration Routine
- 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 Testing
- 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 Systems
- 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

## Ordering Information

Sentinel I System Electrical Safety Test System

Sentinel I System  
Guardian 6100 Plus Safety Analyzer  
CaptivATE Software

Includes:  
G42 Barcode Scanner  
RS232 Cable  
USB to RS232 Adapter

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

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