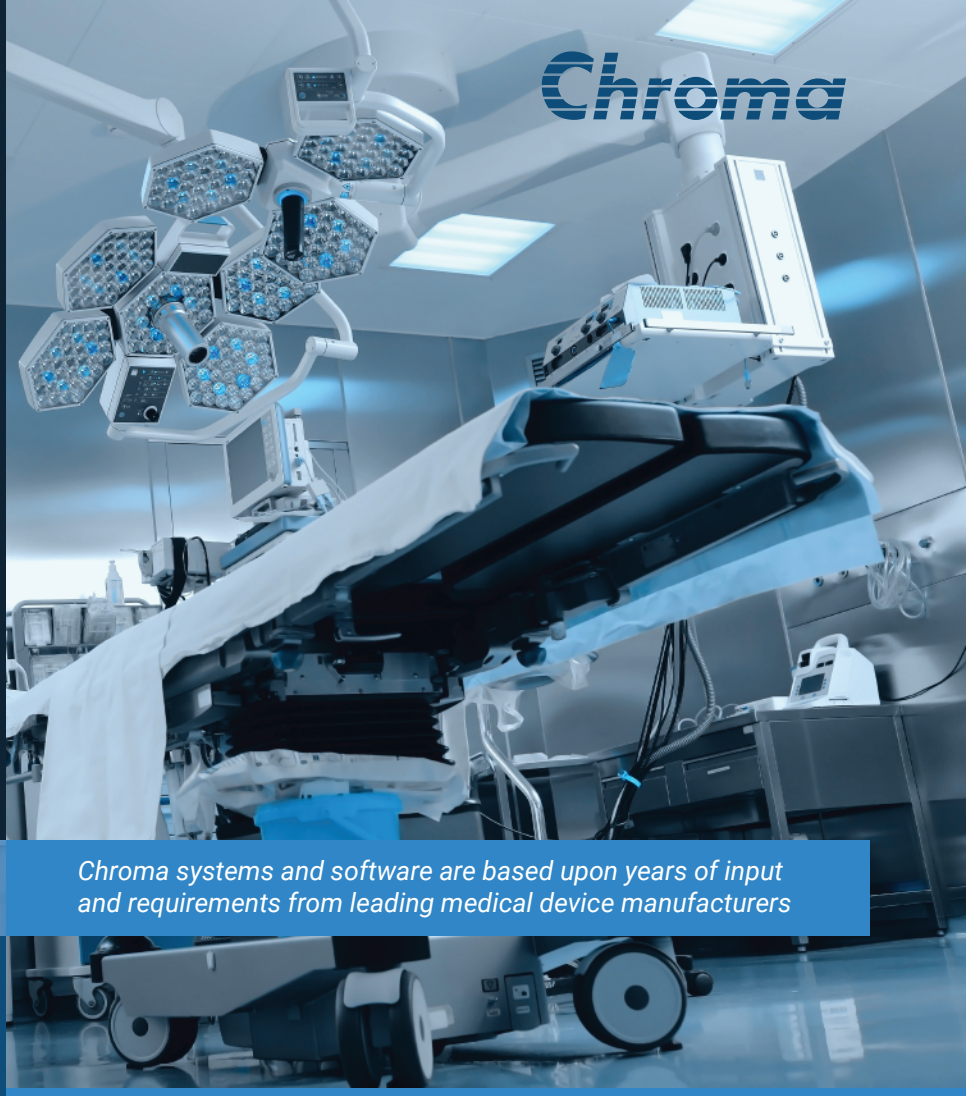
MEDICAL DEVICE TEST

IEC 60601-1
IEC 60601-2-49

AUTOMATED TEST SOLUTIONS



Chroma systems and software are based upon years of input and requirements from leading medical device manufacturers

SENTINEL TEST SYSTEMS

Chroma Sentinel Systems are designed specifically for automated medical device testing to IEC60601-1 and IEC60601-2-49 (Multifunctional Patient Monitoring Equipment) standards.

An integration of Chroma's best in class test equipment and powerful CaptivATE automation software, Sentinel Systems accommodate Class I, Class II, mains and internally powered medical devices.

Depending on your requirements, Sentinel Systems are available in three cost saving and efficient configurations.

APPLICATIONS

- IEC 60601-1 & IEC 60601-2-XX Testing
- Patient Monitor Testing
- Defibrillator Testing
- Electro-Surgical Device Testing
- Endoscope, Light Source Testing
- Devices with Multiple Patient Connections
- Testing Mains Powered & Internally Powered Devices
- Testing Medical Devices with B, BF & CF Applied Parts

PROVIDES IQ/OQ TEST PROTOCOL DOCUMENTATION

BENEFITS

- Increased productivity - Automatic loading of test setup with no need to change cables during testing
- Reduces operator interaction and eliminates multiple test stations
- Expandability - add modules to increase number of patient (applied parts) connections
- Creates test sequences, captures data, provides bar code scanning of device model and serial number, automatically recalls test setup based upon model number and saves all data into a database for trending and analysis

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MEDICAL DEVICE TEST SYSTEMS

The ONLY test systems with IQ/OQ test protocol docs built-in

	Sentinel I 1 B-Type Connection	Sentinel II 1 B-Type Connection	Sentinel III 16 B, BF, or CF Connections 4 Signal Inputs/Outputs
			
TEST CAPABILITIES (Class I, Class II, Mains, and Internally Powered medical devices)			
IEC Standards	IEC 60601-1	IEC 60601-1	IEC 60601-1 & IEC 60601-2-XX
Ground Bond	✓	✓	2 points
AC Hipot up to 5kVac	✓	✓	Multipoint
DC Hipot up to 6kVdc	✓	✓	Multipoint
Mains to AP AC/DC Withstand			✓
Insulation Resistance	✓	✓	✓
Patient Leakage	✓	✓	Up to 16 points
Earth Line Leakage	✓	✓	1 point
Enclosure Leakage	✓	✓	4 points
Patient Axiliary Leakage	✓	✓	✓
F-Type Leakage			Up to 16 points
110% Mains on SIP/SOP's			✓
Programmable AC Power		✓	✓
HARDWARE			
19032/-P Guardian Safety Analyzer	✓	✓	✓
AC Power Source		800VA - 2kVA	800VA - 2kVA
Matrix Scanning System			1 - AC Line Module 1 - GBF - 2 Modules Up to 4 General Modules 1 - Earth Module 1 - AC Line - 2 Modules
Isolation Transformer		Supports up to 2kVA	Supports up to 2kVA
Barcode Scanner	✓	✓	1
RS-232 Cable	✓	✓	3
USB - RS-232 Adapter	✓	✓	3
Cables/Adapters for DUT	✓	✓	✓

SOFTWARE

CaptivATE provides an electrical safety test solution for accurately performing automated hipot, leakage current and functional tests. Testing is made simple and fast by automatically downloading the test setup, conducting the required measurements and outputting the test results.

CaptivATE Supports

- IEC 60601-1
- Chroma 19200 / Matrix 8000
- Multi-level password protection
- Microsoft SQL Server
- NI-USB 6525 Digital I/O
- **IQ/OQ Protocol Documentation**

19032/19032-P Guardian
Electrical Safety Analyzer
Sentinel I, II, III

61600 Series
Programmable AC Power Sources
Sentinel II, III

19200
Martrix Scanning System
Sentinel III

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DUT Model #: CSS-ITA-1017_Load_fixture DUT Serial #: 1 Test Name: CSS-ATE-1164_Verification_Test	Test Result Pass	Test Date: October 02, 2020 Test Time: 2:44:11 PM Operator: admin Setup Name: CSS-ATE-1164_Config

********** TEST RESULTS **********

Step #	Mode	Output	Measure	Offset	Calc/Real	Result
1	Aux Channels	NA	NA	NA	NA	NA
2	AC Source	NA	NA	NA	NA	NA
3	AC Source	NA	NA	NA	NA	NA
4	Leakage Current	1.685 VA	145.8 µA	NA	NA	Pass
5	Aux Channels	NA	NA	NA	NA	NA
6	Leakage Current	1.680 VA	145.8 µA	NA	NA	Pass
7	Aux Channels	NA	NA	NA	NA	NA
8	Leakage Current	1.679 VA	145.8 µA	NA	NA	Pass
9	Aux Channels	NA	NA	NA	NA	NA
10	Leakage Current	1.679 VA	145.8 µA	NA	NA	Pass
11	AC Source	NA	NA	NA	NA	NA
12	Aux Channels	NA	NA	NA	NA	NA
13	AC Hipot	1.350 kV	120.0 µA	NA	NA	Pass
14	Aux Channels	NA	NA	NA	NA	NA
15	AC Hipot	1.350 kV	120.0 µA	NA	NA	Pass
16	Aux Channels	NA	NA	NA	NA	NA
17	AC Source	NA	NA	NA	NA	NA
18	Earth Leakage: Class I	NA	NA	NA	NA	NA
19	Leakage Current	1.683 VA	150.7 µA	NA	NA	Pass
20	Earth Leakage: Class I	NA	NA	NA	NA	NA
21	Leakage Current	1.682 VA	150.7 µA	NA	NA	Pass
22	Earth Leakage: Class I	NA	NA	NA	NA	NA
23	Leakage Current	1.560 VA	150.7 µA	NA	NA	Pass
24	Earth Leakage: Class I	NA	NA	NA	NA	NA
25	Leakage Current	1.680 VA	150.7 µA	NA	NA	Pass

26	Earth Leakage: Class I	NA	NA	NA	NA	NA
27	Leakage Current	1.557 VA	150.7 µA	NA	NA	Pass
28	Earth Leakage: Class I	NA	NA	NA	NA	NA
29	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
30	Earth Leakage: Class I	NA	NA	NA	NA	NA
31	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
32	Earth Leakage: Class I	NA	NA	NA	NA	NA
33	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
34	Aux Channels	NA	NA	NA	NA	NA
35	Earth Leakage: Class I	NA	NA	NA	NA	NA
36	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
37	Earth Leakage: Class I	NA	NA	NA	NA	NA
38	Leakage Current	1.680 VA	150.7 µA	NA	NA	Pass
39	Earth Leakage: Class I	NA	NA	NA	NA	NA
40	Leakage Current	1.680 VA	150.7 µA	NA	NA	Pass
41	Earth Leakage: Class I	NA	NA	NA	NA	NA
42	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
43	Earth Leakage: Class I	NA	NA	NA	NA	NA
44	Leakage Current	1.680 VA	150.7 µA	NA	NA	Pass
45	Earth Leakage: Class I	NA	NA	NA	NA	NA
46	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
47	Earth Leakage: Class I	NA	NA	NA	NA	NA
48	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
49	Earth Leakage: Class I	NA	NA	NA	NA	NA
50	Leakage Current	1.679 VA	150.7 µA	NA	NA	Pass
51	AC Source	NA	NA	NA	NA	NA
52	Aux Channels	NA	NA	NA	NA	NA
53	Ground Bond	NA	NA	NA	NA	NA
54	Ground Bond	25.00 A	169.000 mΩ	NA	NA	Pass
55	Ground Bond	NA	NA	NA	NA	NA

56	Ground Bond	25.02 A	170.200 mΩ	NA	NA	Pass
57	Ground Bond	NA	NA	NA	NA	NA
58	Ground Bond	25.00 A	172.300 mΩ	NA	NA	Pass
59	Ground Bond	NA	NA	NA	NA	NA
60	Ground Bond	25.00 A	171.300 mΩ	NA	NA	Pass
61	Ground Bond	NA	NA	NA	NA	NA
62	Ground Bond	25.02 A	173.400 mΩ	NA	NA	Pass
63	Aux Channels	NA	NA	NA	NA	NA
64	Ground Bond	NA	NA	NA	NA	NA
65	Ground Bond	24.99 A	70.600 mΩ	NA	NA	Pass
66	Ground Bond	NA	NA	NA	NA	NA
67	Ground Bond	25.00 A	71.700 mΩ	NA	NA	Pass
68	Ground Bond	NA	NA	NA	NA	NA
69	Ground Bond	25.00 A	73.900 mΩ	NA	NA	Pass
70	Ground Bond	NA	NA	NA	NA	NA
71	Ground Bond	25.00 A	72.600 mΩ	NA	NA	Pass
72	Ground Bond	NA	NA	NA	NA	NA
73	Ground Bond	25.00 A	74.700 mΩ	NA	NA	Pass
74	Aux Channels	NA	NA	NA	NA	NA

Click here to see the entire test report

**********TEST DETAIL**********

Step #1 NI USB 6525 Aux Channels
Aux 1=0, Aux 2=0, Aux 3=0, Aux 4=0, Aux 5=0, Detect Interlock=0

Step #2 AC Source 61603-31015 AC Source
Voltage (V)=0, Frequency (Hz)=60, Voltage Limit (V)=1, Current Limit (A)=1, Slew Rate (V/ms)=1, Overcurrent Delay (sec)=1

Step #3 AC Source 61603-31015 AC Source
Voltage (V)=132, Frequency (Hz)=60, Voltage Limit (V)=140, Current Limit (A)=2, Slew Rate (V/ms)=1, Overcurrent Delay (sec)=1

Step #4 Guardian 6100 Plus / Chroma 19032 + A190308 Leakage Current
High Limit (mA)=6.000, Low Limit (mA)=0.001, Test Time (sec)=1.0, Device=D4: UL60601-1, Line=L0: Normal, Ground Switch=OFF: Open, Meter=M0: L-G, Power=VA, Power High Limit=4, Power Low Limit=0, Dwell Time (sec)=1, Scanner #1 6000-07 (internal) N/A,N/A,Off,N/A,N/A,N/A,N/A,N/A