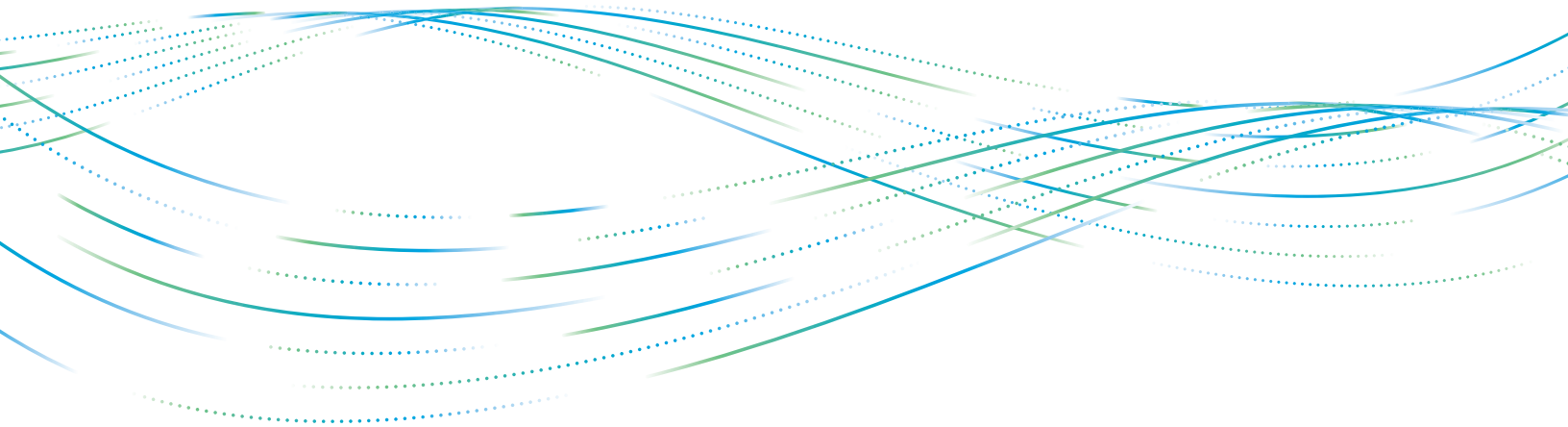
APPLICATION NOTE

Using an S14-09 Load Box to Verify The Performance of a Safety Analyzer

19032/19032-P with Leakage Current Module, Sentinel I, II & III, C8000 Safety ATS

06/05/2023



Products

Guardian Electrical Safety Analyzer 19032/19032-P with Leakage Current Module, Sentinel I, II, III, C8000 Safety ATS

Abstract

Recently there have been a number of medical device manufacturers inquiring about how to verify if their leakage safety tester is functioning properly. Governing bodies like UL and TUV are requiring manufacturers to perform a daily check on the equipment being used to perform safety tests on their medical devices.

This application note discusses a method for confirming that earth leakage, enclosure leakage and /or patient leakage measurements within the safety analyzer are correct. This method will determine whether the measurement circuitry in the safety analyzer is within tolerance as specified in the data sheet. It will also ensure that the device under test (DUT) will be safe and fully functional when it gets to the end user.

It is recommended that a quick verification test on the safety analyzer is performed on a daily basis. With a known load and a known applied voltage, the unit will display the leakage current on the front panel. The safety analyzer powers the DUT and monitors the leakage current from Line to Ground and from Line to the Enclosure of the DUT. In addition, most safety analyzers display the test voltage, current draw and power rating from the DUT.

How can one be certain the displayed test result is correct?

If the safety analyzer is displaying an incorrect value, there is a chance for serious injury to the end user. Current will flow through any conductive path back to Ground, if provided. If the DUT does not have a good insulation barrier, and the safety analyzer displays an incorrect Pass result, it will be hazardous for the end user to come in contact with the DUT when the DUT is powered on. Therefore, you must verify that the DUT has a good insulation barrier (i.e., one that separates the power line from all other circuit components) to prevent the current from flowing back through the end user to Ground.

To ensure that the proper voltage is being applied and that the measurement circuitry is working properly, the S14-09 load box provides a very simple verification test.

S14-09 Load Box Verification Tool

This load box is based on Ohm's law. Custom high quality standard resistors are installed as follows:

Line to Ground blade (R1)
Neutral to Ground blade (R2)
Binding post to Line (R3)
Binding post to Neutral (R4)

The installation configuration applies to the Pass (Green) and Fail (Red) terminals on the S14-09 load box. With this setup the operator can perform the verification test under these four test conditions:

Normal Polarity Earth Leakage (R1)
Reverse Polarity Earth Leakage (R2)
Normal Polarity Enclosure or Patient Leakage (R3)
Reverse Polarity Enclosure or Patient Leakage (R4)

The S14-09 will check the functionality of the safety analyzer for an earth leakage current test and enclosure or patient leakage current tests.

A typical leakage current test is performed at 110% Mains voltage. For North America this is 132V. According to IEC 60601-1 the specified earth leakage current limit for normal conditions is 0.5mA.

Using custom resistors based on the voltage requirement and high limit specification, the load box can produce a specific leakage current to determine whether or not a tester is functioning properly. If the tester is not outputting the correct voltage the desired current will not be produced, resulting in the detection of a problem.

Figure 1: S14-09 P/F Load Box

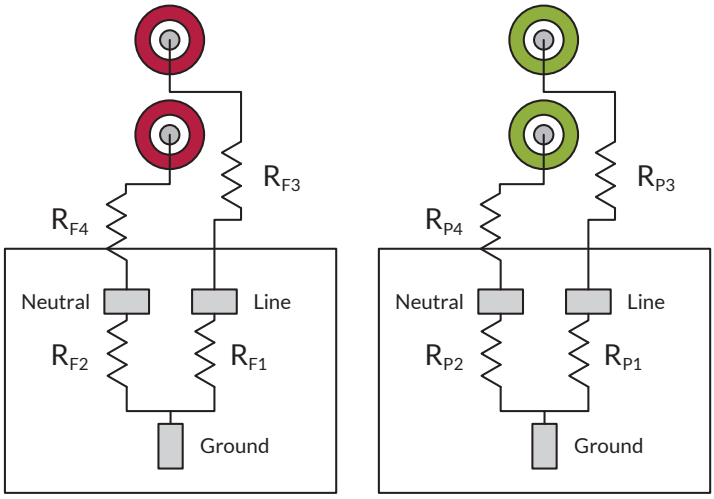


Figure 2: Internal Circuit of S14-09

The following will apply if the tester is functioning properly under:

1. Normal Earth Leakage Current Condition

$R_{P1} = 300k\Omega$
$R_{F1} = 300k\Omega$
$V = 132V$
$I_{High} = 0.5mA$

$$I_{PASS} = \frac{V}{R_{P1}} = \frac{132V}{300k\Omega} = 0.44mA$$

$0.44mA < 0.5mA =$ PASS

$$I_{FAIL} = \frac{V}{R_{F1}} = \frac{132V}{200k\Omega} = 0.66mA$$

$0.66mA < 0.5mA =$ FAIL

2. Reverse Earth Leakage Current Condition

R_{P2} = 150kΩ
R_{F2} = 100kΩ
V = 132V
I_{High} = 1.0mA

$$I_{PASS} = \frac{V}{R_{P2}} = \frac{132V}{150k\Omega} = 0.88mA$$

0.88mA < 1.0mA = PASS

$$I_{FAIL} = \frac{V}{R_{F2}} = \frac{132V}{100k\Omega} = 1.32mA$$

1.32mA < 1.0mA = FAIL

3. Normal Enclosure or Patient Leakage Current Condition

R_{P3} = 1500kΩ
R_{F3} = 1000kΩ
V = 132V
I_{High} = 0.1mA

$$I_{PASS} = \frac{V}{R_{P3}} = \frac{132V}{1500k\Omega} = 0.088mA$$

0.088mA < 0.1mA = PASS

$$I_{FAIL} = \frac{V}{R_{F3}} = \frac{132V}{1000k\Omega} = 0.132mA$$

0.132mA < 0.1mA = FAIL

4. Reverse Enclosure or Patient Leakage Current Condition

R_{P4} = 300kΩ
R_{F4} = 200kΩ
V = 132V
I_{High} = 0.5mA

$$I_{PASS} = \frac{V}{R_{P4}} = \frac{132V}{300k\Omega} = 0.44mA$$

0.44mA < 0.5mA = PASS

$$I_{FAIL} = \frac{V}{R_{F4}} = \frac{132V}{200k\Omega} = 0.66mA$$

0.66mA < 0.5mA = FAIL

This will hold true for all conditions which shall be tested. The table below shows the resistor values for each test condition in order to produce a pass and fail.

Resistor Values for Each Test Condition

Resistor	Condition	Test Voltage (V)	Specified Limit (mA)	Nominal Resistance (kΩ)	Calculated Current (mA)
R_{P1}	Earth Normal Pass	132	0.5	**300**	**0.440**
R_{P2}	Earth Reverse Pass	132	1.0	**150**	**0.880**
R_{P3}	Enclosure/Patient Normal Pass	132	0.1	**1500**	**0.088**
R_{P4}	Enclosure/Patient Reverse Pass	132	0.5	**300**	**0.440**
R_{F1}	Earth Normal Fail	132	0.5	**200**	**0.660**
R_{F2}	Earth Reverse Fail	132	1.0	**100**	**1.320**
R_{F3}	Enclosure/Patient Normal Fail	132	0.1	**1000**	**0.132**
R_{F4}	Enclosure/Patient Reverse Fail	132	0.5	**200**	**0.660**

Conclusion:

It is good manufacturing practice to test the safety analyzer daily. By using the S14-09 load box, you can monitor any shift of the safety analyzer out of tolerance. The S14-09 load box ensures that the safety analyzer will not display false results when testing products. By using the S14-09 as a verification tool with a known load, the safety analyzer will be able to display the leakage current measurement along with the applied test voltage. With this method you can verify the performance of the safety analyzer, including any isolation transformers, the power sources and the test cables.