

Chroma Systems Solutions, Inc.

# Electrical Safety Testing of Medical Electronic Equipment

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**19032 Electrical Safety Analyzer + A190308 Hipot/Line Leakage/Probe Scanner  
(20A)**

Keywords:

19032-GB Electrical Safety Organizer, Ground Continuity Testing, Ground Bond Testing, HIPOT Testing, Line Leakage Current Test, Earth Leakage, Enclosure Leakage, Applied Part Leakage, Current Draw & Power Consumption.

# Electrical Safety Testing of Medical Electronic Equipment

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*Title:*

*Product Family:* **19032-GB Electrical Safety Organizer + A190308 Hipot/Line Leakage/Probe Scanner (20A)**

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## Scope

Manufacturers of medical electronic equipment must be sure that their products are safe from electrical hazards to the patient and to the caregivers. There are a number of UL, European, and Canadian standards that serve as the ruling body on how medical products will be tested, one in particular, IEC60601-1 (the International Electrical Safety Standard for medical electronic equipment) is experiencing “global harmonization,” meaning it is being accepted and implemented around the world.<sup>1</sup> The IEC60601-1 standard is mainly intended for product development, where safety considerations must be taken into account early in the design phase of a product. However, it is also applied to production line testing since it is the only way for a manufacturer to be sure they are shipping a safe product.

There are a number of areas of safety testing, which include leakage current, dielectric breakdown, insulation resistance, and ground bond testing. To understand the differences in these tests and others, we will examine the purpose and techniques for each.

## Are You Grounded?

Following visual inspection, the ground continuity and ground bond tests should be the first electrical safety tests on consumer appliances as well as medical products. The tests check the connection from any exposed or accessible metal parts to the earth reference on the product’s line cord. The ground continuity and ground bond tests are often a prerequisite for the Hipot Test. It is wise to verify the ground integrity of the product before applying high voltages that might jeopardize the test operator.

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<sup>1</sup> Referred to in the USA as UL2601-1, in Canada as CSA C22.2 No.601.1, and in Europe as EN60601-1.

## Ground Continuity Testing

Many product standards require that the presence of ground continuity connection be verified during production testing. One way of doing this is with a low current “ground continuity test,” which verifies that the connection is present. Verifying the presence of this connection is one thing, but to ensure that it is capable of handling high current is the purpose of the “ground bond test.”

## Ground Bond Testing

The low current continuity test is adequate for safety testing of many products but not for medical equipment. The ground bond measures the resistance of the ground connection, to determine whether sufficient current will flow to earth through this connection (not through the operator) in the event that a product should fail and a user accessible surface come in contact with a live voltage.

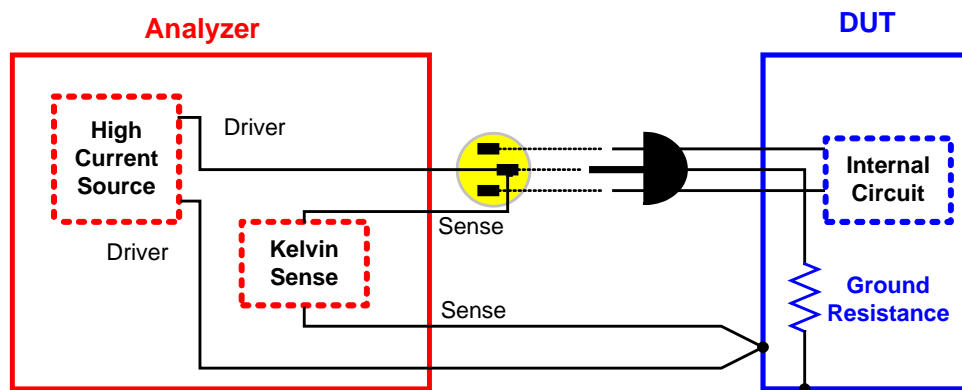


Figure 1: Setup for Ground Bond Test

IEC601-1 states that user-accessible conductive parts connected to the safety ground be tested with a current of 25 Amps or 1.5 times the product’s current consumption, whichever is greater. This current shall be from a source with a max. no-load voltage of 6 volts AC. Other medical standards allow the max. voltage up to 12 volts, AC or DC. The 12V limit is to protect the test operator from hazardous voltage levels. The resistance of this ground path is the important parameter. It is calculated from the test current and voltage drop and should be less than 100mΩ on equipment with detachable power cord, or 200mΩ with permanently attached power cord.

## HIPOT Testing

The Hipot test, often called the voltage breakdown or dielectric withstand test, performs an electrical stress test on a product’s insulation beyond what it might encounter in normal use. The rule is to apply a test voltage two times the normal operating voltage plus 1000V (~1250 or ~1500 VAC depending whether the product operates at 115 or 240 VAC). This is usually an AC voltage, but in some cases a DC voltage, higher by a factor of 1.414, can be substituted. For products with permanently attached power cords, the test voltage is applied between the high (hot) and neutral conductors shorted together and power ground or exposed metal parts. During this test the product’s power switch is in the “on” position, but the product is not powered up and running. Refer to Figure 2.

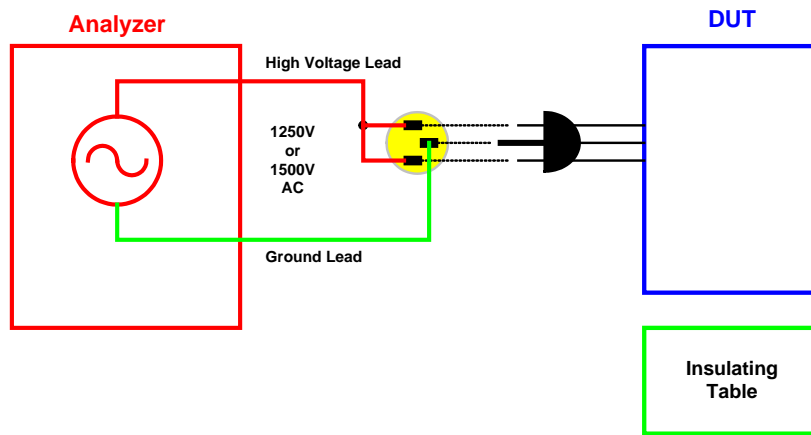


Figure 2: Typical AC Hipot Test

The test voltage is raised from zero to the predetermined test voltage and typically held for 1 minute. No breakdown—a rapid increase in current across the tested insulation—should occur. Most Hipot analyzers allow the operator to program maximum and minimum current levels. Besides the maximum limit, above which the product is considered to have failed, a minimum current limit indicates whether the analyzer is properly connected to the device under test.

## Line Leakage Current Test

The Hipot test detects **leakage** current through a product's insulation system as the result of a deliberate over-voltage condition. A test for **line leakage** current is something quite different. The line leakage test detects leakage current at normal operating voltage while the product is turned on and powered up. Line Leakage is a series of tests that monitor the leakage current produced by a product while it is operating. The input voltage to the product is normally 110% of the highest rated mains voltage. A Line Leakage test can include any or all of the following: Earth Leakage, Enclosure Leakage, and Applied Part tests. The leakage current levels are monitored through a measuring device (MD) which simulates the impedance of the human body. The tests conducted on the products are performed during both normal and single fault conditions.

The line leakage test is intended to measure current flow through the following parts of the product:

- Through the ground system
- From the product enclosure to ground
- In, out, or between parts accessible to the patient

Excessive currents result in an electrical shock to the user or patient. Because of this potential hazard, safety agencies have set standards for the maximum amount of current that may leak from a non-defective product. Line leakage tests are normally specified for the design phase. However, to ensure that a device is safe for the patient and the caregiver, line leakage tests are typically required on medical products in the production phase.

### Earth Leakage

One of the critical tests specified in IEC60601-1 is conducted with a circuit similar to that shown in Figure 3 and known as earth leakage current. The earth leakage current test measures the leakage current flowing from the protective earth of the medical device through the patient (in this case, the measuring device) back to the protective earth conductor of the power cord. This is the total leakage current from all protectively earthed parts of the product. This test applies to Class I devices. The earth leakage current test must be done under “normal” conditions and “single fault” conditions. Normal conditions are electrical conditions that might normally occur on regular basis and are not considered a problem. An example shown in Figure 3 is a “reversed AC line” , simulated by S1.

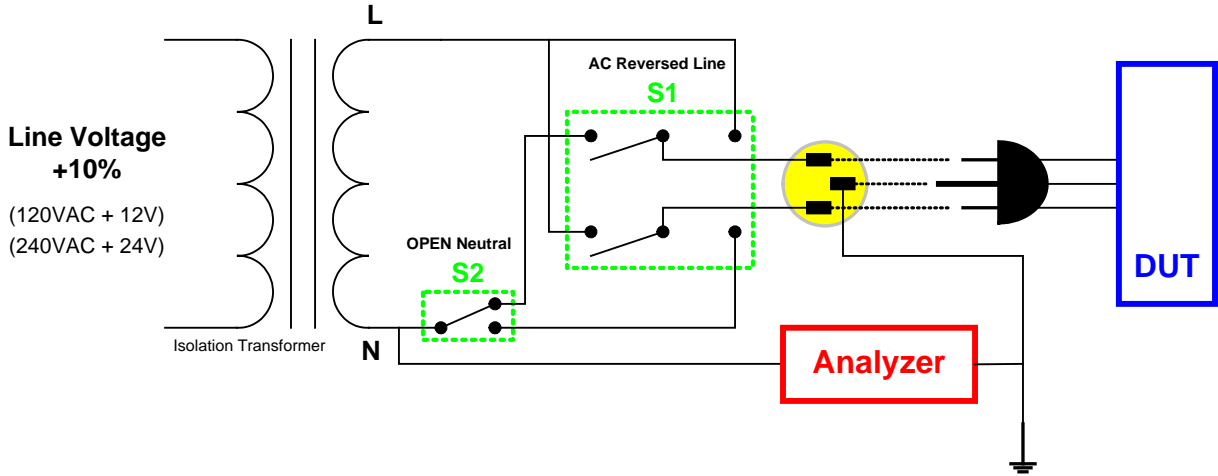


Figure 3: Line/Earth Leakage Test

A single fault is a problem that could occur, and since it is unlikely that two faults would occur simultaneously, faults are tested one at a time. An example of a single fault is an ‘open neutral’, simulated by S2. This test is made with normal and reversed line (S1), and open and closed neutral (S2).

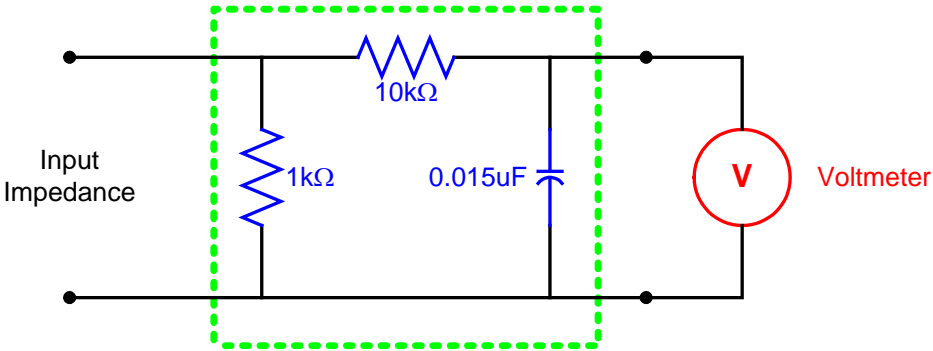


Figure 4: Human Body Equivalent Impedance

An important thing about line leakage measurements is that the standards require the use of analyzers with very specific loads, where the load simulates the impedance of the human body. An equivalent circuit of the human body consists of a  $1\text{k}\Omega$  resistor in parallel with the series combination of a  $0.015\mu\text{F}$  capacitor and  $10\text{k}\Omega$  resistor, as shown in Figure 4.

## Enclosure Leakage

Now referred to as **Touch/Chassis Leakage**, it is the Leakage Current measured from any part of the enclosure through the measuring device to earth, and between any two parts of the enclosure. This applies only to parts of the enclosure not connected to protective earth. Enclosure leakage current is measured during normal conditions as well as during single-fault conditions, in which one supply conductor at a time is interrupted, and, if applicable, the protective earth conductor is opened.

The Enclosure Leakage test measures the continuous leakage current from the enclosure back to the system neutral of Class I and Class II products. On Class I products the test is performed with every combination of open and closed earth conductors, normal and reversed polarity conditions, and with the neutral conductor open and closed. On Class II products a  $10 \times 20$  cm foil is attached to the enclosure and the leakage is measured from the foil to the system neutral under normal and reversed polarity conditions with the neutral conductor open and closed. The foil applied to the enclosure simulates a surface contact with the enclosure approximately the size of the hand.

## Applied Part Leakage

The Applied Part is that portion of the medical product that in normal use comes in contact with the patient. They are often referred to as patient connections. There are three types of applied parts; B, BF and CF. They are classified based upon usage C being cardiac versus non-cardiac and F being floating/isolated from earth ground.

B-type applied parts are non-cardiac grounded applied parts. These are applied parts that come in contact with the patient for the medical device to perform its function. B-type parts are referenced to ground and are not isolated or 'floating' as would be the case in BF or CF applied parts.

An F-type applied part is isolated to such a degree that no current higher than the allowable patient leakage current under a Single Fault Condition flows into it from an application of external voltage source to the patient. F-type Applied Parts are classified as BF (non-cardiac floating applied parts) or CF (cardiac floating applied parts). These parts are tested by applying 110% of the mains supply voltage from an isolation transformer to the F-type AP then measuring the patient leakage current between the isolation transformer and the F-type AP.

## Current Draw & Power Consumption

IEC60601-1 specifies additional tests that verify the normal operation of a product. One is for Current Draw, which measures the current that a device under test is consuming through the power cord. This is done with the power applied and the instrument under normal operating conditions. The actual current must be within 10 to 25% of the rating marked on the product. Another test is for Power Consumption, which measures the power the DUT is consuming while operating. The power consumption should not be more than 10 to 15% above the rated marking on the product. This test should be done with equipment controls set for maximum output and the measurement should be for

### Conclusion

Standards may serve as the basis for shipping safe product into the medical industry, but the ultimate responsibility for these safe products rests with the manufacturer’s test process and type of equipment.

CHROMA produces multi-function electrical safety analyzers for the tests discussed above. Multi-function perform several tests in the same box, including AC Hipot, DC Hipot, ground bond, insulation resistance and line leakage measurements. These multi-function analyzers are now becoming popular in product development or production areas where comprehensive testing must be implemented.

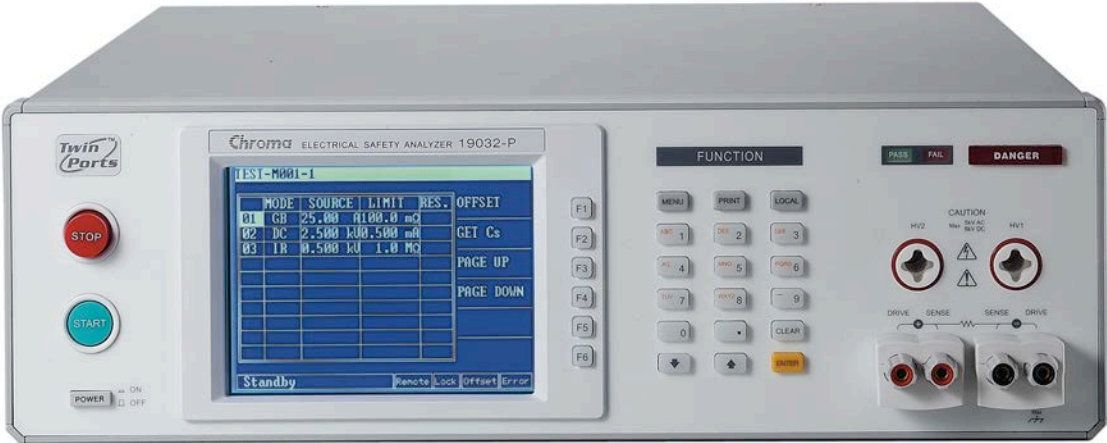


Figure 5: Chroma 19032 –GB Safety Analyzer for Medical Products