

## Making the Connection

Connection to a finished medical device for electrical safety test is straight forward, Mains power to ground. Most dielectric withstand testers (Hipot testers) provide an optional cable which connects the Hipot tester to a mains power plug. Connection to a disposable medical product such as a lead or probe is not as straight forward. Elaborate fixturing is required to obtain a proper connection to the product while ensuring no damage occurs. This application note discusses connection methods to various medical products for electrical safety testing.

## Test requirements

It is important to understand all the tests to be performed prior to designing a test fixture. Common tests that are performed are High Voltage Dielectric Withstand, Insulation Resistance, and Contact Resistance. The test conditions must be known to ensure the fixture can handle the test requirements. For Hipot tests the duration of the test is just as important as the test voltage, some materials can endure a short blast of voltage but will melt if subjected to 500V for a duration. If the product is a medical lead, there is a good chance the contact resistance within the lead needs to be measured. Depending on the lead and resistance a Kelvin measurement may be required.

A Kelvin measurement is a four terminal measurement. It uses a second pair of terminals separating voltage from the supply current to the device under test. This simple improvement of independent leads for voltage and current effectively removes the series inductance and resistance error factor. Accuracy for the lower impedance measurement is substantially improved when using a Kelvin connection.

A Kelvin connection will require additional connections to the fixture so that each point on the lead will have two connections to the tester.

## Test requirement check list

### Dielectric Withstand

Test voltage: \_\_\_\_\_

Test duration: \_\_\_\_\_

Number of points to apply high voltage: \_\_\_\_\_

### Insulation Resistance

Test voltage: \_\_\_\_\_

Test duration: \_\_\_\_\_

Minimum Resistance: \_\_\_\_\_

Number of points to measure: \_\_\_\_\_

### Contact Resistance

Test Current: \_\_\_\_\_

Resistance Reading: \_\_\_\_\_

Number of points: \_\_\_\_\_

## Implantable leads

One of the challenges with an implantable test leads is the numerous types and lengths of leads. Another obstacle is connection to the lead without causing damage. The fixture shown below in Figure 1 is a lead fixture with four distal test points and eight proximal test points. The lever is closed into position making contact between the gold plated pins and test lead. Figure 2 shows the lever open and a clear view of the test pins.

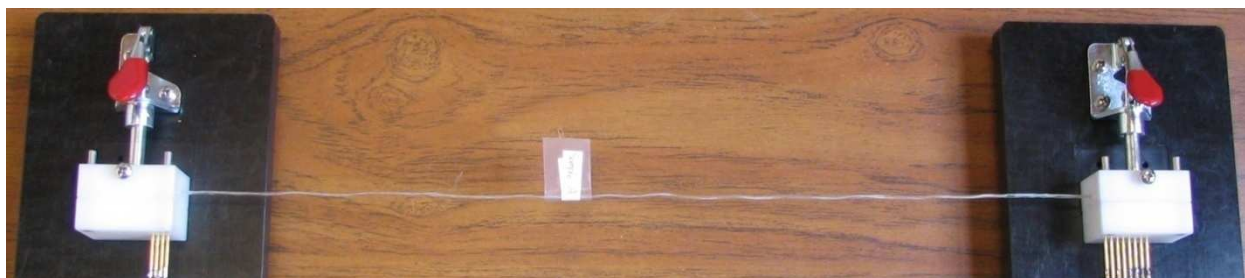


Figure 1. Implantable Lead Fixture in closed position

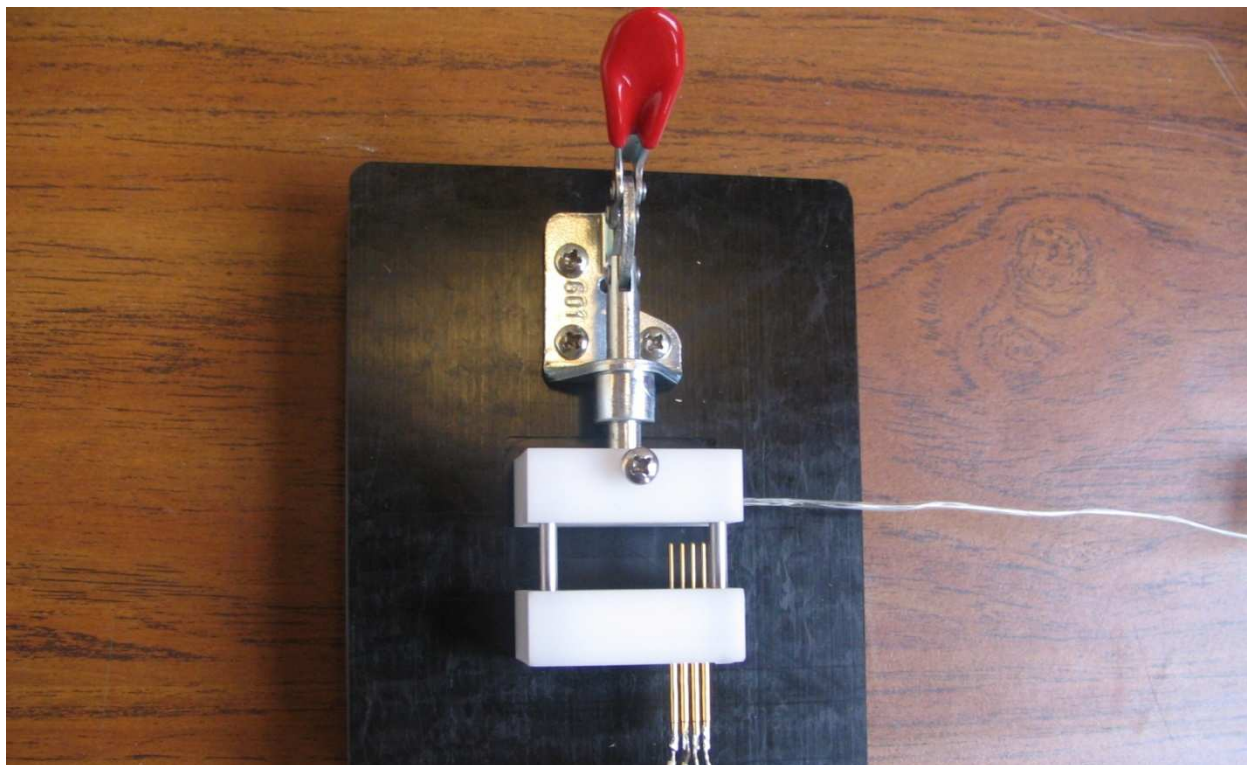


Figure 2. Implantable Lead Fixture in open position

The fixture is constructed of Acetyl (Delrin) and PTFE plastic. This material provides an excellent insulation between each test point and connection to the tester. The movement of the lever is smooth allowing for connection to the test lead with one easy movement. The test points are constructed of gold plated terminals with a rounded edge so that there is no marring or damage to the test lead surface.

Often the test requirement for an implantable lead is Hipot, Insulation Resistance and Contact resistance. This fixture allows for all three of these tests to be performed. The contact resistance measurement was not stringent for this test therefore a two wire measurement was ample.

High voltage wires with sheathing are soldered to the pins shown on the bottom of the figure and then connected to the scanning matrix of the tester.

## Surgical pens

Risk Management is growing in the medical device industry, in 2007 the FDA issued twenty-four Class I recalls (the most serious type). This has resulted in medical device manufactures to implement more stringent tests of their products. Surgical pens and electrodes have a conductor encapsulated by an insulating material. In the past many manufactures would apply high voltage to the conductor and see if there is breakdown of the insulating material to a metal plate. The issue with this test is only half of the insulating material is being tested (the half touching the metal plate). Placing the product in a saline solution and testing between the electrode and saline has also been used. The downfall of this method is the drying and sterilization process required after the test is performed. Other manufactures have wrapped their product in foil to perform the test. This method is acceptable however time consuming in a manufacturing environment.

To improve the foil method a fixture can be milled out of 6061 aluminum. Virgin Teflon insulators are used for test probes to ensure no arcing between the test probes and aluminum occur. The fixture will consist of an upper and lower half connected by hinges. Figure 3 shows the bottom half a fixture where there is a pocket for each electrode to fit into. The fixture can be made in sections to accommodate multiple lengths of electrodes.



Figure 3. Alluminum Fixture for surgical electrode

The underside of this fixture looks similar to the top side providing connection for the high voltage wire to the Hipot tester. The return line of the test is connected to the aluminum casing. This fixture could potentially have high voltage to the casing therefore safety precautions must be taken. A safety enclosure is always a good idea when using high voltage. Figure 4 shows a sample high voltage safety enclosure with an interlock connection. If the door of the enclosure is opened the tester will terminate high voltage immediately.

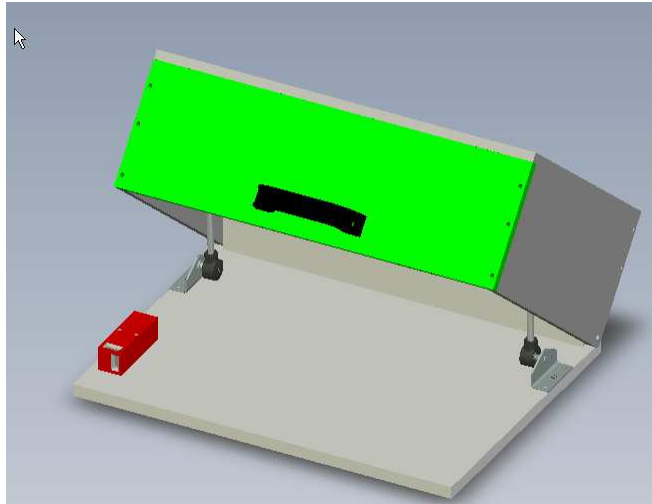


Figure 4.Safety Enclosure

Regardless of the product under test it is important to ensure the operator performing the test is safe. Safety enclosures and interlocks should be used whenever possible. Ensure fixturing to the product is made of material capable of handling the test conditions it will endure.

QuadTech Inc. offers a wide variety of electrical safety and passive component measurement solutions to medical device manufactures. For information visit [www.quadtech.com](http://www.quadtech.com).