QuadTech

Application Note

Hipot Testing Multi-Conductor Feedthroughs Used in Implanted Medical Devices

Feedthroughs used in implanted medical devices (IMD's) such as pacemakers, defibrillators, neurostimulators, and implantable hearing devices make it possible to provide a liquid tight hermetic seal while providing a conduit for wires. Once an IMD is fully assembled, the only way to perform safety testing is via the wires on the external side of the feedthrough. This application note illustrates how to effectively perform electrical safety testing of IMD's with feedthroughs.

Application

Let's start by looking at a typical multi-conductor feedthrough in Figure 1.

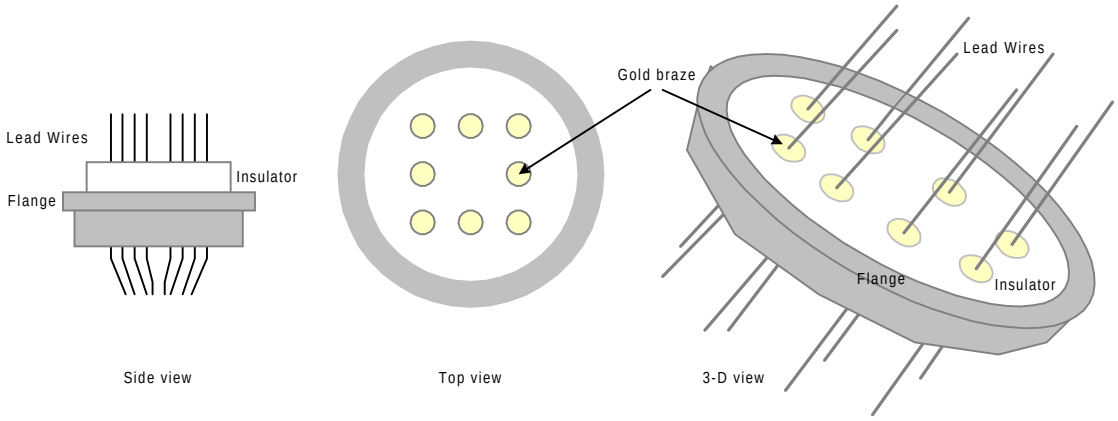

Figure1: 8-Leaded Feedthrough

A typical feedthrough is comprised of lead wires (surrounded by a braze material) fed through an insulator that is set in a flange. Whether the seal is glass, ceramic, or another material, a hipot test and typically an insulation resistance test must be made from each wire to all of the other wires, and to the outer metal portion (braze) of the feedthrough.

Hipot (Dielectric Withstand) Test

Once implanted into the human body, the feedthrough has the chance to be exposed to the shock of a defibrillator. Defibrillators can reach voltages of 3kV or more. One reason for the hipot test is to stress the insulation material to see if there are any flaws in the insulation material. If a feedthrough did not undergo a hipot test, then there is a chance that the product could become damaged due to a defibrillator discharge.

Hipot (Dielectric Withstand) Test

The hipot test applies a voltage (at least 2X the rating of the feedthrough) for a given time period (typically, approximately five seconds). If the feedthrough can pass the hipot test (i.e. low leakage current), then it most likely will be able to perform without failure under normal operating conditions. This seems quite simple, right? But should this test be performed at AC or DC?

One advantage of AC is the applied voltage is testing the material with a positive and negative voltage. It can also accelerate the breakdown in flawed material much faster. Another advantage of AC is that it can be used to check for installed capacitors. Refer to application note "Testing Filter Capacitors on Medical Devices" (035127) for details on how to implement this process.

The disadvantage of AC is that if there is a capacitor or the material is capacitive across the test points, then there will be a very high reactive leakage current, which may cause damage. However, if implementing the process of application note 035127 then a high AC voltage is not applied when checking the material. This particular AC hipot test of filter capacitors applies a small amount of AC voltage to check the installation and value of the installed capacitor.

One advantage of DC hipot testing is that if the material or device being tested is capacitive, then the DC test would be less damaging due to much lower leakage current. A pending breakdown in the insulation material can be detected before damage is done by slowly incrementing the test voltage and monitoring the charging current. If there is a capacitor, thyristor, or diode connected to the wire, then DC may be the only available means for checking the voltage rating of these devices.

The disadvantage of DC testing is that it can be time consuming. When applying a DC voltage to a highly capacitive device or material, the voltage must be raised slowly over time and ramped down slowly over time to keep the charging/discharging current to a minimum.

Insulation Resistance Test

The insulation resistance test typically applies a DC voltage of 1000V or less, then measures the actual resistance of the insulation material in ohms (Ω).

This test should be performed before AND after a hipot test. Why? Since a hipot test can be destructive, performing an insulation resistance test before and after will provide a means to ensure the integrity of the insulation material was not compromised.

But please keep one thing in mind. Medical devices, including feedthroughs, have extremely low leakage currents. When measuring very high resistance levels on the order of 30GΩ at 1000V, the leakage current is 33nA. This means that it becomes necessary to provide good electrical shielding on the cabling and test fixtures to avoid electrical noise coupling.

Scanner Application

Speed, efficiency, and ease of use are three of the most important factors to consider when setting up a test station. For multi-conductor feedthroughs, implementing a scanner is the best way to accomplish this.

If you had a tester with only one output channel, and you had to test each wire to the others and to the outer metal portion of the feedthrough, you would have to press “start”-“stop”-reconnect the wires-“start”-“stop”-reconnect the wires…and on and on…This would be a VERY time consuming and labor intensive task. Let’s take a look at how we can implement a scanner so that all you have to do is press “start”-“stop” one time.

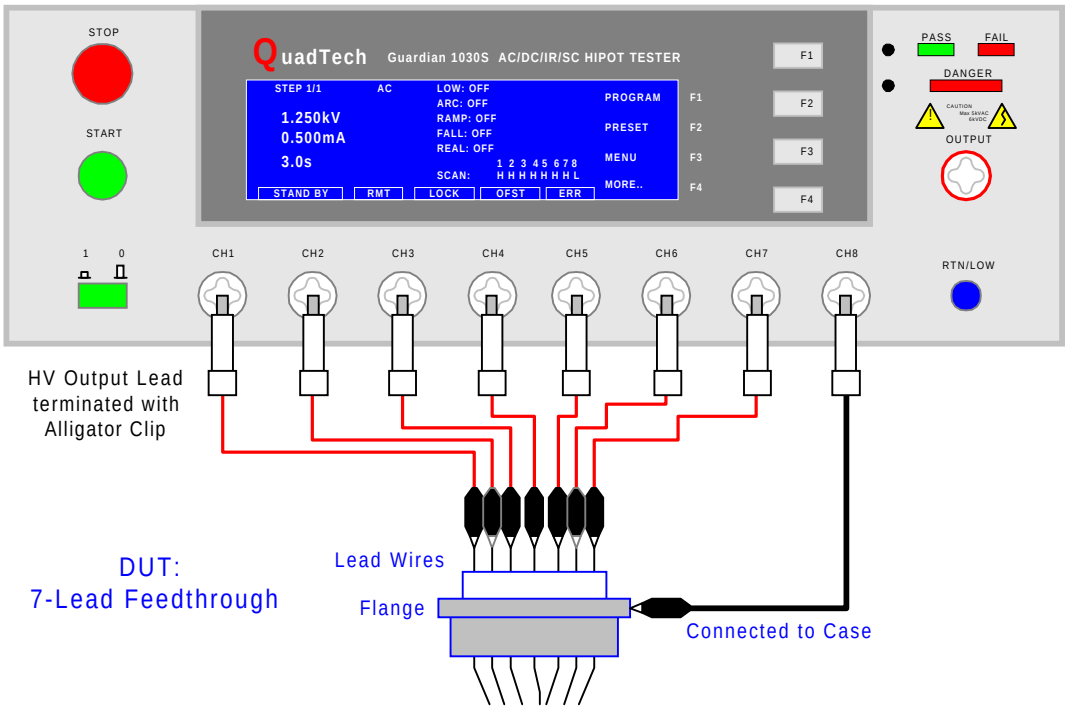

Figure 2: Feedthrough Connection to G1030S Hipot Tester

Using the QuadTech Guardian 1030S as illustrated in Figure 2, a feedthrough with up to eight connections (conductors/lead wires) can be attached to the eight scanner connections. Each output of the scanner can be configured as a High Voltage Output (H), or a Return (L) connection.

Utilizing this capability allows the instrument to perform AC/DC Hipot and IR measurements in any combination of connections. Measurements can be made from one lead to another lead in any combination. For example, to conduct a test of each lead, a test could be stored into memory to scan lead 1 to lead 2, lead 1 to lead 3, … lead 3 to outer case, lead 2 to lead 3, etc…To possibly speed things up a bit, you may be able to run a test lead 1 to lead 2, 3, 4, 5, 6, 7 and case, lead 2 to lead 3, 4, 5, 6, 7, and case, and so on until each lead is tested to the other.

Now, if the feedthrough is already assembled into a medical device and you want to check for the existence and/or value of a capacitor installed inside the medical device, you can implement the process discussed in the “Testing Filter Capacitors on Medical Devices” application note.

Summary

The G1030S AC/DC/IR Hipot Tester can provide a simple and cost effective solution to testing feedthroughs without the need of manually switching connections.

If the feedthrough you are testing requires more than eight connections, then the Guardian 6000 Series of instruments may be a better solution to speed the testing of your feedthroughs. These instruments provide the ability to connect one internal scanner with eight channels plus up to seven more external scanners with eight channels each. This allows testing up to 64 different channels!

Utilizing the scanner capability of one of these testers along with the built-in IEEE or RS232 communication capability provides the speed, efficiency, automation, and testing capabilities required for your application.

For complete product specifications on QuadTech's Electrical Safety Testers or any of QuadTech's products, visit us at http://www.quadtech.com/products. Call us at 1-800-253-1230 or email your questions to info@quadtech.com.

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