QuadTech

Application Note

Testing Filter Capacitors on Medical Devices

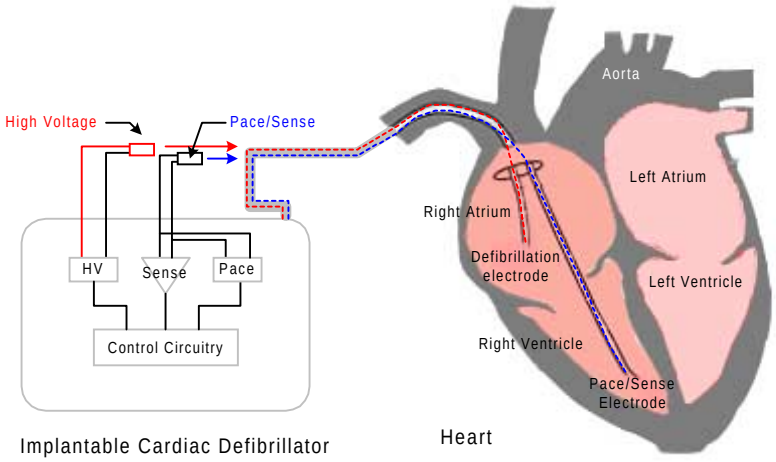
Hipot testing medical devices with EMI filter capacitors is quite a simple test. However, there is another capability of your hipot tester that you may not be aware of. It can be used to perform a Capacitance Verification test. Once a medical device is fully assembled, the hipot tester is connected to the exterior connections of the device (SIP/SOP, patient leads, etc). This is like looking into a "black box" not knowing what is being tested on the inside of the medical device.

Typically, there is an EMI filter capacitor attached directly to the wire on the interior side of an implanted medical device (IMD). But what if the capacitor is not installed properly? You would not be able to know this by simply performing a DC Hipot or Insulation Resistance Test. While applying a DC voltage does ensure the capacitor or the circuit is not shorted, it does not indicate if the capacitor is disconnected or the wrong value. Capacitors used in the medical industry typically have extremely low leakage current. It becomes very hard to distinguish between a capacitor with very low leakage current and a capacitor that is not internally connected.

This application note will show how the hipot tester can be used not just as a means to check the DC Leakage Current or the Insulation Resistance, but can also be used to verify the existence and the value of a capacitive filter.

Application

For example, look at a simple diagram of an implantable cardiac defibrillator (IMD) in Figure 1.



An IMD consists of a pulse generator with a battery, timer and sensing device in it and one (or two) insulated leads that are inserted into the heart chamber. The leads conduct the electrical pulse from the generator to the heart chamber to stimulate a heartbeat (muscle contraction). The leads also sense the heart's natural electrical pulse and impedance and send that back to the generator. Thus the leads have a Pulse and Sense function. The Sense Input wires typically have a connection to an EMI Filter Capacitor.

Capacitance Verification

To check the Insulation Resistance or Leakage Current from the wire to the outside case of the pacemaker, a DC voltage must be applied between the two. If an AC Hipot test is used then the leakage current passes right through the capacitor. However, if we consider the impedance characteristic of a capacitor:

$$(1)\ X_C = -1/2\pi fC$$

f = frequency of AC signal
C = capacitance

We can determine the existence and the value of the capacitor installed by applying a known voltage and frequency and measuring the current.

If we assume a capacitor with very low dissipation factor it is possible to neglect the real portion (R) of the total impedance (Z) in the formula:

$$(2)\ Z = R + jX_C$$

Neglecting R yields: $(3)\ Z = jX_C$

Substituting (1) into (3) gives: $(4)\ |Z| = 1/2\pi fC$

Using Ohm's Law we see: $(5)\ V = I \times |Z| = I \times 1/2\pi fC$

Let's assume we have a 3000pF EMI filter capacitor on the input of the Sense Input (+), and an AC Hipot Test of 100Vac. Substituting these values and rearranging formula 5 gives us a current:

$$I = VC2\pi f = (100V)(3000pF)(2\pi)(60Hz) = 113.1\mu A$$

This is the current that should be expected if the 3000pF capacitor is installed. Setting the Hipot tester High Current Limit slightly above this value, and the Low Current Limit slightly below this value will give PASS/FAIL criteria. If the leakage current fails high, then the capacitance installed was too big. If the leakage current fails low, then the capacitance installed was too low, or not installed at all.

Summary

This test would typically be done as the step before the DC Hipot or IR test. When using a hipot tester capable of storing multiple steps per test, the AC Hipot (or in this case Capacitance Verification) test can be stored and used as a step in the same hipot test routine. This simple step can be an extremely effective method to check the actual capacitance installed inside an IMD or any medical device requiring filter on the input lines, decreasing the risk of shipping a defective product.

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.