Inspections, Compliance, Enforcement, and Criminal Investigations

Electronic Components - Resistors

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DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

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ITG SUBJECT: ELECTRONIC COMPONENTS - RESISTORS

This ITG has been written to familiarize the Investigator with one of the electronic components commonly used in medical devices. This ITG covers theory, application, and testing of the resistor and some of the design considerations that should be made when using resistors. If sufficient interest is shown for this approach, additional components will be covered in future ITG issues.

Theory

Resistors are devices manufactured specifically to provide a fixed or variable resistance to fit a particular electrical circuit application. The function of a resistor or resistance can be simply explained by using an analogy between a variable resistor in a series circuit, with additional fixed resistors, and a valve in a waterline. Assume that we have a single adjustable valve in a water line connected to a source of water at some pressure. As you know, we can reduce or increase water flow through the line by partially closing or opening the valve. Similarly, if we have an adjustable resistance in an electrical circuit, we can effectively reduce or increase current flow in the circuit by increasing or decreasing the circuit resistance. The water pressure in the water line is analogous to voltage in the electrical circuit. As we progressively open the water valve the water flow increases and the pressure differential across the valve decreases until there is no significant pressure difference between each side of the valve when the water valve is fully open. Similarly, as we decrease the resistance of a variable resistor (open the valve) the voltage differential across the resistor decreases until, as we reach the end of the resistance (where we have essentially a short circuit) there is no appreciable voltage differential across the resistor. The voltage differential across the resistor at any point in time is termed the "voltage drop". As the valve is progressively closed, the pressure differential across the valve increases until, with the valve fully closed and no waterflow, the pressure differential across the valve is the same as the pressure at the source. Similarly, let's assume we have a resistor that we can adjust to a very large value. As we increase the resistance, the voltage differential across the resistance increases until at the maximum value of the resistor (representing an open circuit) there is essentially no current flow through the resistor and the voltage at the resistor is the same as at the voltage source. The absolute validity of the analogy as stated is affected by other circuit factors, but the analogy is close enough for our use.

Probably the simplest formula to be learned when working with electricity is Ohms Law -.

Voltage (V) = Current (I) X Resistance (R)

Another way to write Ohms Law is -

Voltage (V) Current (I) = -------------- Resistance (R)

Using this formula it is easy to see that as the total resistance (R) is decreased (assuming voltage is constant) the current (I) will increase. Conversely, as the resistance is increased, the current will decrease. Appropriately, the unit of measure for resistance is ohms. Voltage is an electromotive force and may sometimes be designated by the letter

"E" in the formulas given.

Application

Resistors are utilized to make the output of one circuit compatible with the input of another (impedance matching), to introduce resistance into an electrical or electronic circuit to set the amount of current to be used (loading), set voltage and current operating levels for active components such as transistors (bias), and to limit current flow and reduce voltage for many other applications. The volume control on your car radio, TV, or stereo is an adjustable resistor.

Types of Resistors

There are basically two resistor types regarding mode of operation; fixed and variable. As the names imply, a fixed resistor has a fixed value and a variable resistor can be varied or adjusted to different resistance values. Schematic symbols for fixed and variable resistors are as follows:

(Symbols)[4]

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Commercially available resistors commonly used in medical devices can be further sub-divided into three basic types according to construction technology; composition, wire-would and film. These basic resistor technologies differ in size, cost and electrical characteristics. The type that is selected for a particular design depends on the size limitations and electrical parameters needed and the environment in which the resistor is expected to operate. Some are better than others for particular purposes, no individual type has all the best characteristics.

Composition - Composition resistors are probably the most common resistors used and are made by combining a resistive material, such as carbon, with a binder. The binder is used to hold the carbon together so that it can be molded or formed into various desirable shapes.

Due to inconsistencies in materials and methods used in the manufacture of resistors, all resistors have a specified permissible deviation (specified in percent) of the manufactured value from the specified "nominal" value at stated environmental conditions (usually at 25 C). This specified deviation is called "tolerance". Every resistor has a specified tolerance range over which the resistance value is allowed to vary; anywhere from approximately 0.1% to 20% of the nominal value. Most resistor applications will allow tolerance variations, but for those resistors used in critical positions where a tight or restricted resistance tolerance is necessary, any change in parameters that causes them to vary beyond their selected values could result in a defective product (±1% or less would be considered a tight tolerance).

The composition resistor is considered a general purpose resistor. Typically, composition resistors are available in tolerance from ±5% to ±20%. Composition resistors should not be used in critical applications where environment changes can be expected. The effects of humidity, temperature and pressure, as well as normal aging, can cause the composition resistor to vary as much as ±15% or more outside its specified tolerance range.

Wire-wound - The wire-wound resistor is considered one of the most stable resistors, with commercially available tolerances as low as ±.1%. Wire-would resistors are constructed by winding a resistive wire around an insulated form and covering the end product with an insulating material.

Film - Film resistors are made by forming a thin layer of resistive material onto an insulated form. The most commonly used film resistors can be divided into types according to the materials used: carbon-film, metal-alloy and metal-oxide. One popular metal film resistor is manufactured by applying a metal film onto a cylinder of ceramic. One of the commonly used materials for these resistors is "cermet". Cermet is a combination of ceramic and metal materials, hence the name "cermet."

One of the latest film resistor technologies is the manufacture of thick and thin film resistors, which are used in microelectronic and hybrid circuits. Thick film resistors are formed by stenciling a resistive metallic paste or ink onto a base in much the same way that silk screening is done. Usually the resistive materials are considered proprietary. Thin film resistors are formed by vapor deposition of a thin layer of resistive material onto a base. Thick and thin film resistors are normally trimmed to a specific value by etching away resistive material using lasers, sandblasting, etc.

Most composition and wire-would fixed resistors are packaged in a cylindrical form with axial leads. Thick and thin film resistors are manufactured in a variety of shapes and sizes. Film resistor networks are packaged in plastic dual-in-line packages (DIP), single-in-line packages (SIP), flatpack packages and round metal packages identical to those in which integrated circuits are packaged. Individual resistors may be packaged in chip and pellet form. A chip, as used in microelectronics, is any small (usually square or oblong) piece of material that contains a circuit or component. Thick film resistors are commonly used in hybrid circuits where they are deposited directly onto the circuit substrate. A substrate is a tiny platform on which circuitry is deposited. Thick and thin film resistors have found many applications in the development of microelectronics because they can be made smaller than other comparable value resistor types. Film resistors are often used in critical positions in circuitry. They can be purchased off-the-shelf with minimum tolerance of ±0.1%, exhibit little change in value with changes in temperature, and are usually stable under humidity and pressure changes.

Power Resistors - Power resistors are required to carry large quantities of current and subsequently dissipate a lot of heat. Consequently they are usually larger than those that are designed to carry smaller current quantities. Power resistors are usually encapsulated in materials that aid in the dissipation of heat and are usually designed so they can be mounted to a heatsink or equipment chassis to facilitate heat removal by conduction. Common power resistors may be composition, wire-wound, or film resistors.

Variable Resistors - A variable resistor is commonly referred to as a "pot"; meaning a potentiometer. A potentiometer contains an element of continuous resistive material with a sliding contact that traverses the element in a circular or straight line, depending on the potentiometer style. It is normally adjusted by a shaft connected to a dial or thumbscrew, or by a screw-driver or adjustment tool. Variable resistors may be wire-wound, composition or film resistors. Small, precision, adjustable resistors are called "trim-pots" and are used for fine adjustments in low current applications. Variable resistors that are constructed to carry large values of current or power are called "rheostats" and are commonly used for adjusting motor speeds and oven and heater temperatures.

Resistors usually have markings indicating value, tolerance and sometimes composition and reliability rating. Reliability rating is given as a failure-rate in percentage failure per 1000 hours of operation. These values may be written on the resistors or may be provided in color code as shown on the carbon composition resistor in Figure 1. (Figure) The color code is usually provided by four or five color bands (represented by the variation in color shades in the black and white photo) around the body of the resistor. An interpretation of this color code is given in Table 1. The color code given is the military standard general code for color bands or dots used on electronic parts and used by most manufacturers.

Figure 2 (Figure) depicts some resistor types commonly used in medical device circuitry. As you can see, the metal film, wire- wound and composition resistors on the left look essentially alike. This makes it extremely difficult to identify resistor construction by simple observation, unless the observer is familiar with the manufacturer's product. The variation in size within each resistor group shown is due to variation in power rating and value. Usually, within a resistor type, the higher the power rating (watts) the larger the resistor. For example, the power ratings of the carbon composition resistors shown varies from 1/4 watt (smallest shown) to 2 watts (largest shown). But a particular wattage in one resistor type may be larger or smaller than the same wattage in another type. For example the largest carbon composition resistor shown is 2 watts, while the wattage of the wire- wound resistor directly above it is 3 watts, although the carbon resistor is slightly larger than the wire-wound resistor.

Table I - Color Marking Code (MIL-STD-1285A)

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          1st Color  2nd Color   3rd Color   4th Color     5th Color, Failure
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Color	1st number	2nd number	Multiplier	Tolerance	Rate Level Symbol
Black	0	0	1	±20%	L (As specified)
Brown	1	1	10	± 1%	M (1%/1000)
Red	2	2	100	± 2%	P (0.1%/1000)
Orange	3	3	1,000		R (0.01%/1000)
Yellow	4	4	10,000		S (0.001%/1000)
Green	5	5	100,000		
Blue	6	6	1,000,000		
Violet	7	7	10,000,000		
Gray	8	8	---		
White	9	9	---		
Gold	-	-	---	± 5%	
Silver	-	-	---	±10%	

Determine value by starting with color closest to end of resistor. If colors equidistant from both ends, begin at end farthest away from gold or silver (tolerance) band.

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Testing

The proposed Medical Device GMPs would require that electronic components when appropriate, be inspected, sampled, and tested for conformance with specifications. If the finished device is a critical device, and a resistor is used in a critical position, the proposed GMPs would require individual testing of critical resistor lots, either 100% or on a sampling basis. The following resistor tests are those which may be conducted routinely by manufacturers of critical medical devices.

Resistance Value - The value of the resistor is measured using an ohmmeter or resistance bridge to verify the resistance value is within the tolerance specified in the resistor specifications. Resistor values are normally given in Ohms (X1), Kilohms (X1000) or Megohms (X1,000,000). Typical tolerances range from ±0.1% to ±20%.

Resistance to solvents - Some firms conduct a solvent resistance test to verify that the component markings will no be discolored or removed when subjected to production cleaning solvents. The test is also conducted to verify that the solvents will not damage the component material or finish.

Solderability - The purpose of the solderability test is to determine if the component leads are receptive to the soldering process. Basically this test determines if solder will adhere completely to the component leads.

Burn-in - This test is sometimes conducted on thick and thin film resistors and resistor networks (See ITG#19).

The proposed GMPs would require that all instruments used to measure the acceptability of components be calibrate per written procedures.

Failure Modes

Resistor failures are considered to be electrical opens, shorts or a radical variation from the resistor specifications. The failure modes experienced vary with the type of construction. A fixed composition resistor normally fails in an open configuration when overheated or overly stressed due to shock or vibration.

Excessive humidity may cause an increase in resistance. A variable composition resistor may wear after extensive use, and worn away particles may cause high resistance short circuits. Wirewound resistors may experience open windings due to overheating or stress, or short circuited windings due to accumulation of dirt, dust, breakdown of the insulation coating or high humidity. Film resistors fail for the same reasons as wirewound and composition, but have also failed due to changes in resistive material characteristics resulting in reduction and increase in resistance value.

Design Considerations

The following information is provided to assist the Investigator in evaluating resistor failures and the proper use and incorporation of resistors into a medical device. These are guidelines only, as there are no official standards or regulations covering these areas. These are some of the factors the manufacturer should consider during the design phase and if not considered, could easily lead to a defective device.

When evaluating the proper use of resistors in a design, temperature is one of the most important considerations as overheating is the major cause of resistor failure. The effect of too much heat is usually not immediate, but if sustained usually results in a deterioration over a period of time until at some point the resistor fails, usually resulting in an open circuit. If the resistor is a critical component, it may result in catastrophic failure of the device into which it is incorporated.

In addition to contributions from the environment, resistors generate their own internal heat because they present a resistance to current flow. This internal heat is an energy or power loss which the resistor absorbs and dissipates. The energy loss is measured in "watts" and each resistor is rated in watts according to how much power it can safel dissipate. This "power rating" is usually established at an ambient temperature (usually 25 C) and takes into consideration how much the internal temperature of the resistor will rise with rated power applied.

Although most electronic component manufacturers specify their product's electrical parameters at 25 C very few components actually operate at temperatures this low after incorporation into an operational device. This is particularly true with power circuits, such as used in power supplies. Normally medical device electronic circuits are contained in some sort of enclosure. The combined heating effects of all the circuit components inside the enclosure soon raises the internal air temperature well above 25 C. Often the resistor is the major contributor of this heat, especially when large power resistors are used when power supplies are a part of the device. When resistors are required to carry substantial currents they should be positioned with consideration given to the effects their self-generated heat will have on neighboring components. The heat from a hot resistor may cause a neigh-boring borderline component to fail prematurely. Power resistors, which must dissipate a lot of heat, must be properly "heat sinked" and situated so cooling air circulates freely about the resistors. Heat-sinks are usually "fluked" or "vaned" metal fixtures on which components are mounted to aid in removal of heat from the device by conduction. Sometime components are mounted directly onto the device's metal chassis and the chassis acts as the heat sink. Sometimes a cooling fan is necessary in addition to the heat sinks. Preferably, resistors should be mounted so that dissipated heat can be immediately exhausted, and not blown across other components. An electronic component that operate in a cool environment will last much longer than a hot component and the device's reliability will be improved.

When power supplies are incorporated into a device or high voltages are generated, "heat distribution" studies shoulc be made within the device enclosure during the prototype design stage. If hot spots or excessive temperatures are measured, cooling fans, air vents, power supplies, etc., should be located to eliminate the adverse conditions.

If the medical device is to be used in an operating room, where explosive gases are used, flammability of resistors may be an important factor to consider. If they get hot enough, some resistors will actually burst into flame. An example is the carbon composition resistors which are used in all electronic devices. If flammability is a factor, the designer should specify a requirement for flammability resistance when ordering components.

All electronic components, including resistors, should be mounted so that they are restrained from movement relativ to the selected mounting base. Most medical devices are subject to vibration and shock and if not mounted securely components can short circuit against neighboring components or leads and connections may be weakened or broken. If components designed to be mounted horizontal to the mounting surface must be stood on end, the leads should b insulated to prevent short circuits. Components should also be mounted to preclude collection of dirt and moisture between conductors that might result in short circuits.

Electrical parameter changes due to other environmental variations and aging must be taken into account when designing an electronic device. Fluctuations may cause the restricted tolerances of a critical component to drift out of prescribed limits resulting in the medical device varying outside its operating limits.

The resistor is a simple component in that it performs no active function, and it has been historically the most reliabl component used in electrical circuitry. But in the past few years, due to the economic situation and increases in cos of materials, a multitude of resistive materials have been introduced for use in resistors, especially thick and thin film Often the user does not know the identity of the materials used, as some are proprietary. All resistors can not be expected to function reliably unless their reliability has been established through long use in the selected application or through extensive qualification and testing.

References:

1. MIL-STD-199B Selection and Use of Resistors
2. MIL-STD-202E Test Methods for Electronic and Electrical Component Parts
3. MIL-STD-1285A Marking of Electrical and Electronic Parts

Common Resistor Types[9]

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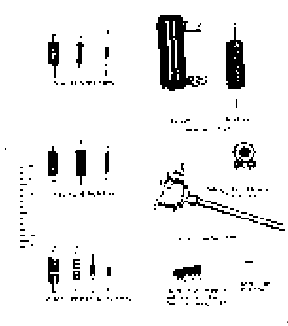

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15. http://wcms.fda.gov/FDAgov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/default.htm
16. ssLINK/UCM072906.htm