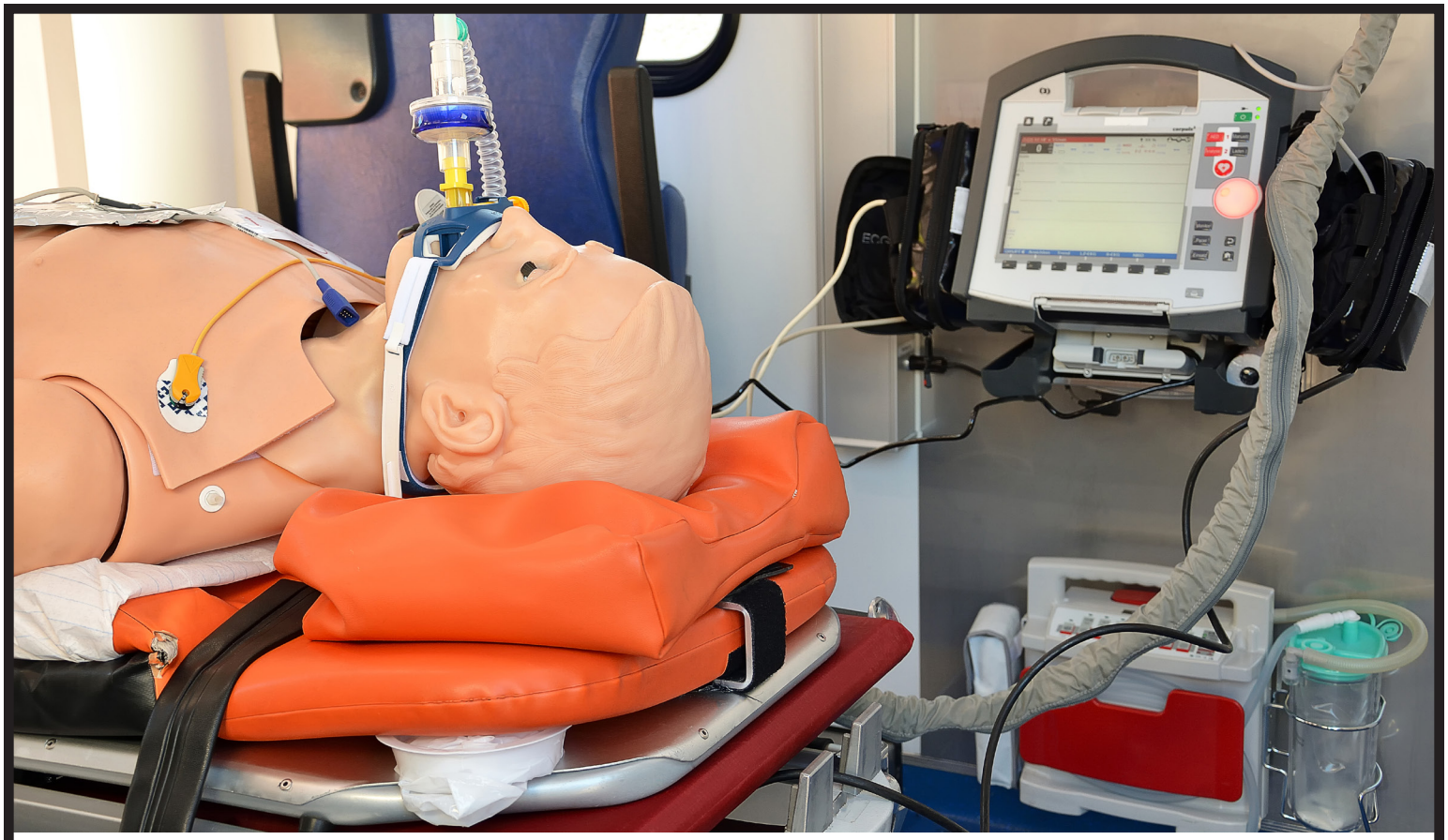


THE IMPORTANCE OF RELIABILITY IN THERMAL CONTROLS FOR MEDICAL EQUIPMENT

This Whitepaper touches on ways to build more reliability into essential equipment used in hospitals, assisted living facilities and medical clinics. Acknowledging the dire results from catastrophic failure in these products, this paper shows ways to build reliability in the devices used to provide safety or control in the electrical circuits that power medical equipment.

This Whitepaper should be read by:

- Design Engineers for medical equipment
- Engineering and Production Managers for medical equipment manufacturers
- Procurement personnel for medical equipment manufacturers
- Hospital procurement personnel
- Regulatory agency personnel

This Whitepaper will explain:

- How thermal controls provide both over temperature protection and temperature control.
- How to spot potential reliability problems in the thermal controls you spec.
- How to assess the potential reliability of the thermal controls you spec.
- How to customize thermal controls to more precisely meet the needs of your application.
- How to taking derating into account when specifying thermal controls.

THE IMPORTANCE OF RELIABILITY IN THERMAL CONTROLS FOR MEDICAL EQUIPMENT

By: **Portage Electric Products, Inc.**
7700 Freedom Ave. NW, P.O. Box 2170
North Canton, OH. 44720 USA
p: (330) 499-2727 • f: (330) 499-1853
salesinfo@pepiusa.com
www.pepiusa.com

Table of Contents

In the spring of 2020, as a pandemic swept the world and we witnessed the true value of reliability in essential medical equipment. The pandemic provided a graphic life or death example of the importance reliability plays in any part designed to protect electrical circuits from catastrophic failure.

We have built an entire product line designed to be more reliable than any other thermal protectors available. As a result, PEPI® thermal controls are found in a large percentage of the vital medical equipment used to fight the pandemic. Here are some of the things we've learned about building reliable thermal control solutions.

Defining Reliability

When it comes to thermal control solutions reliability means the ability of a device to break a circuit to stave off catastrophic failure, every time. This means environmental concerns cannot interfere with a thermal control's operation. It means heavy usage or circuit irregularities cannot lead to thermal control disfunction. It means manufacturing processes cannot let out-of-spec pieces slip through. The very nature of medical equipment means failure is not an option.

However, as we have seen in over 65 years manufacturing thermal controls for use in medical equipment, reliability is as much a function of design as manufacturing. A poorly designed device will not reliably perform in the real world, no matter how well it is manufactured. Conversely, a well-designed device will accommodate some manufacturing variation, but will not reliably overcome sloppy manufacturing and quality procedures.

Thermal control manufacturing is an exacting process demanding precise equipment and well-integrated quality procedures. But, if you were to perform a root cause analysis on the most reliable thermal controls, you would find a corporate dedication to reliability above all else. There are no cutting corners on the procurement of quality, dependable materials. Product designs put reliability first. Manufacturing systems are arranged with full knowledge that thermal controls will be put to work in a wide variety of environments and must be customizable in order to maintain needed levels of reliability in every device.

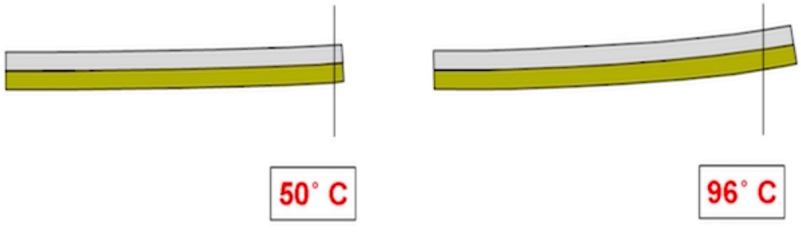
This white paper is about what it takes to make thermal controls reliable enough to meet the severe performance challenges of modern medical equipment where catastrophic failure can mean people die. However, catastrophic failure in appliances, automobiles, transformers, small motors and other products can have equally devastating consequences for people who use them and manufacturers who make them.

First, Consider How Thermal Controls Operate

Thermal controls either break a circuit when the temperature is getting too hot for the application (over temp protection) or they regulate the temperature by continuously breaking and making the circuit (temperature control). In both instances, the purpose is essentially the same — keep things from getting out of control.

There are three essential elements that enable a thermal control to do its job. (1) Connectors to the circuit entering and exiting the device. (2) The circuit breaker (thermal controller). (3) The case or outer structure designed to protect the device circuitry from dirt and ambient disruptions.

The second of these elements, the circuit breaker thermal controller, is the most important. It can be designed to work one-time, breaking the circuit when circuit temperature rises too far, or it can be designed to be repeatable, breaking the circuit when the temperature exceeds a pre-set level and remaking the circuit when the temperature drops to another preset level, allowing the product to continue working. The most common circuit breaking device in a resettable thermal control is a bimetallic element where one side of the metal contracts as the circuit temperature rises forcing the element to open the circuit. As the temperature cools, the element bends in the opposite direction, closing the circuit when it touches the contact. Resettable thermal controls therefore introduce a fourth critical component, the contact where the element meets the circuit.



It's important to know that any of the four essential components of a thermal control can be customized in any number of ways to make the control more responsive and reliable in any particular application, including yours.

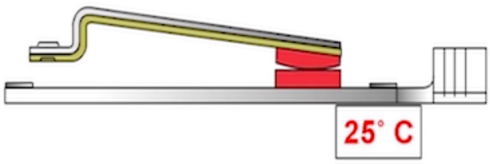
The Stepping Stones of Medical Device-level Reliability

There are three steps that must be taken to ensure high-reliability thermal controls. All are important and affect the performance of the four essential components that go into every thermal control.

1. **Designing for Reliability**
   Performance and reliability follow design. There are three things you can look at to judge whether a thermal control is designed to maximize reliability:

   Will it fit neatly into the application: When a thermal control is positioned into a narrow space trouble is around the corner. With space at an increasing premium in most product designs, miniaturization is one key to thermal control reliability. However, the drive to create smaller and smaller thermal controls does have a downside if manufacturers don't have the design and manufacturing capabilities to precisely fit thermal control components into tight spaces.

   How are critical circuit contacts designed? In resettable controls the ability of bimetallic elements to reliably make the circuit is critical. Contacts therefore become one of the most important components. However, these contacts tend to wear or develop a tarnished coating during the stress of repeated make and break cycles. For this reason, contacts should be designed with consideration of the wear, tear and stresses they will face in any given application. PEPI® thermal control designers developed ways to ensure solid contact despite the ravages of repeated make and break cycles. By allowing the use of different bimetallic elements and precious metal contacts PEPI® versatility allows thermal controls to be more closely matched to the stresses and sensitivity needs inherent in any individual application.



   Can the control be customized to better suit your application? No two circuit applications are exactly alike. Some require enhanced sensitivity or protection from ambient temperatures. Others may need to make or break a circuit in a narrower range that cannot be accommodated by standard configurations. Most thermal controls cannot be customized beyond calibrating operating temperature, due to either design considerations or lack of interest by the manufacturer.

   Those that do allow full customization tend to perform most reliably. Bimetallic elements can be changed to enhance sensitivity. Cases can be protected from ambient temperatures or isolated from electrical circuits in any number of ways. Leads can even be configured to speed production in your own factory.

   The bottom line is controls best suited to your application will perform most reliably.

2. **Component Quality**
   The component that can most easily be beset with quality problems is the bimetallic element. Each bimetallic element needs to be made from high quality metals at precisely the right thickness and dimension, with the metal alignment oriented properly. The metals used to form the element must also be reliably adhered so that the actions of one side are

precisely mimicked by the other. Finally, any coatings need to be properly applied so that the metal element creates a reliable circuit when touching the contacts. There are many bimetal suppliers, but only a handful that can reliably deliver the quality strips of specified bimetal used to manufacture high-precision elements for resettable thermal controls.

Contact quality is also a core issue when manufacturing reliable thermal controls. In addition to using high-grade silver, contacts may need to be gold infused in low voltage applications where corrosion resistance is important. Silver supplies the best conductivity, while gold provides the best corrosion resistance.

Finding the right alloy and ensuring the contacts are welded perfectly will greatly improve the reliability of a thermal control's performance.

3. **Quality Testing**
   When reliability is most important, statistical quality control practices may not yield the best results. These type of quality programs will tell you how many parts can be expected to be out of spec, but will not weed out the bad ones. When manufacturing medical equipment, you can't afford those out of spec parts to be included in your final product.

   The better choice is some form of full quality inspection. We say some form because cost is obviously going to be a factor. In medical equipment, where a bad thermal control could cause dangerous malfunction, you need to require some type of advanced statistical quality control. This should include some type of statistical quality control system comprehensive enough to identify first piece article inspection through a full batch process analysis. When it comes to the reliability required for medical and similar equipment, this level of quality scrutiny is required.

Environmental Concerns Affecting Reliability

Every thermal control has two faces. The first is the way it acts in a testing lab, under ideal conditions. The second is the way it acts in the real world where ambient temperatures and resistivity conspire to cause bimetal to react at lower temperatures. This is called derating and understanding its effects can play a large role in establishing greater reliability in your products.

Resistivity, the measure of how strongly a material opposes the flow of electric current, causes heat to build up within the bimetal element. This built up heat causes the metal to react by opening a circuit before reaching the calibrated temperature. Since the design objective of a thermal control is to anticipate heat build-up and shut the circuit down quickly before catastrophic failure can occur, derating allows you to anticipate how a device will behave in conditions closer to those in the real world. For this reason, manufacturers concerned with reliability will provide full derating testing and information to support your choice of thermal control. A fuller explanation of this effect can be found in our previous white paper *"Derating For Real World Conditions."*

The mounting and positioning of thermal controls in an application can also have a dramatic effect on reliability. Thermal controls react to two different stimuli. First is current in the circuit creating heat as it builds up. The other is ambient temperature. In fact, some product designs demand thermal controls react to one or the other. However, misplacement of the control, especially in over-temperature applications, can be adversely affected by ambient temperatures generated by motors or trapped heat in different areas of the product. Often the solution to premature tripping is to move the thermal control to a different mounting location within the product.

The Commitment Required to Ensure Reliability

Every manufacturer sets up their product design, procurement and manufacturing processes to achieve a certain goal. Some target becoming the low-cost supplier in an industry. Others specialize in one type of thermal control or another. Others design their products for mass manufacturing hoping to capture the high-volume end of the market.
Manufacturers, like Portage Electric Products, Inc., who have staked their future on the reliability of their products, must make a corporate-wide commitment to building the most reliable thermal controls possible. Reliability demands no compromises in any part of the design and manufacture of thermal controls.

Designs have to be optimized for safety and reliability in heavy use environments.

Procurement has to find and build relationships with manufacturers of high quality, dependable components.

Manufacturing has to develop and constantly maintain innovative machinery capable of repeatable precision in every movement with built-in quality controls.

Quality has to be invasive enough to eliminate out of spec parts before shipment.

Engineering has to be both knowledgeable and versatile enough to help customers customize the thermal controls they select to more precisely match the needs of their application.

Customer Service has to understand how to effectively interpret customer needs in order to get engineering started on the right foot.

Above all else, Corporate Executives have to resist the temptation to take their eye off the target and start cutting costs rather than investing in better ways to build reliability.

Medical Equipment Leads the Way

An odd thing happened in the pandemic that reared its ugly head in early 2020. We found out that during our more than 65 years of existence, many customers turned to PEPI® to help them achieve the reliability their products required. For quite some time we had to adjust and adapt our production schedules to accommodate the manufacturers of essential equipment. However, this just reinforced to us the importance of decisions we made many years earlier.

Over the years, Portage Electric Products, Inc. has pioneered innovations that helped us become the market leader in terms of reliability. The first PEPI® products were built to be safe, but their real triumph was their miniaturization. As time moved on, we came to recognize the increasingly important role PEPI® products play in protecting products,— ranging from transformers to coffee makers,— from catastrophic failure.

We don't use the word "catastrophic" lightly. If medical equipment fails, lives can be lost. But the results can be equally harsh if a power drill ignites from an overheated circuit, or a lighting ballast explodes for the same reason. Any product with an electrical circuit is a potential landmine for the people who use them as well as the people who make them. The role of thermal controls is to prevent such catastrophic failures, whether the controls are used for over-temp protection or temperature control. As time progressed, we increasingly saw the important role PEPI® products played in protecting our customers' products from catastrophic failure.

NOTE: We are happy to provide customer assistance and technical advice in a variety of areas. We appreciate the opportunity to assist you and to better understand your needs; however, since Portage Electric Products, Inc. does not possess full access to data concerning all of the uses and applications of customer's products, we cannot assume any obligation or liability for information we provide or the results you might obtain.

Certain aspects should be taken into consideration when applying both creep and snap action devices. Careful attention must be paid to input voltage, load currents, and the characteristics of the load. Final design criteria should be based upon results of the testing of our devices in your application at your facility.

Portage Electric Products, Inc. is a privately owned company whose primary focus is building our reputation for reliability. Manufacturing thermal controls among the most reliable in the world is our only business providing us both the focus and means to continue using reliability as our North Star. If reliability is an important consideration in your selection of a thermal control, let's talk.

To inquire about PEPI® thermal controls, visit www.pepiusa.com, or contact us at salesinfo@pepiusa.com.

We come through when the heat is on®

Pepi®

Portage Electric Products, Inc.

PEPI® PROTECTED™