Heating Devices Should Enhance Operation Of Medical and Diagnostic Equipment

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Hypothermia is a condition where body temperature falls below 35°C (95°F) and normal bodily functions are unable to take place. In stage-two hypothermia, shivering becomes more violent and muscle mis-coordination occurs. This condition would obviously be difficult for a healthy person, but it could be highly stressful for a patient receiving medical care and testing.

Injecting fluids into a patient at room temperature and in post-operative recovery can reduce body temperature. Ideally, medical practitioners want perfect conditions for patient recovery and therefore have been paying close attention to optimum temperature in new medical device designs.

This article explores how electric heaters are used to enhance the operation of various forms of medical and diagnostic equipment. Preventing mild hypothermia is only one of the reasons for adding a heat source to your equipment. Heat may also be used to incubate cultures, add warm humidity to respiratory equipment, heat fluids before injection into the body, stabilize equipment performance, enhance surgical procedures, sterilize instruments and a myriad of other applications.

With the diversity of applications, it becomes obvious that a wide variety of heater technologies and designs are needed to meet performance requirements. Since we are addressing human, animal or plant organic matter, most applications require a stable process temperature of about 98.6°F (37°C). However some applications, including cell incubation and sterilization, may require higher temperatures.

For obvious reasons, patient safety is paramount in equipment and heater design. Design considerations for safety will include electrical (low leakage current), fire, gas or particulate outgas and temperature stability. Medical and diagnostic equipment is covered by several regulatory organizations including FDA, UL® and CE.

First, let’s define the scope of an electric heater. In its most basic form an electric heater is simply a resistive wire, foil or film element that gets hot when electricity is applied. For most medical applications, an open wire is an impractical solution. Therefore, a more complete heater or thermal subassembly is required. A more practical form of a heater includes the heater element, electrical insulation, lead wires and a mounting method. For safety in medical applications, a redundant over temperature device may be incorporated into the heater. A thermal subassembly may include a heater plus other electro-mechanical components that, in combination, improve the equipment design and performance.

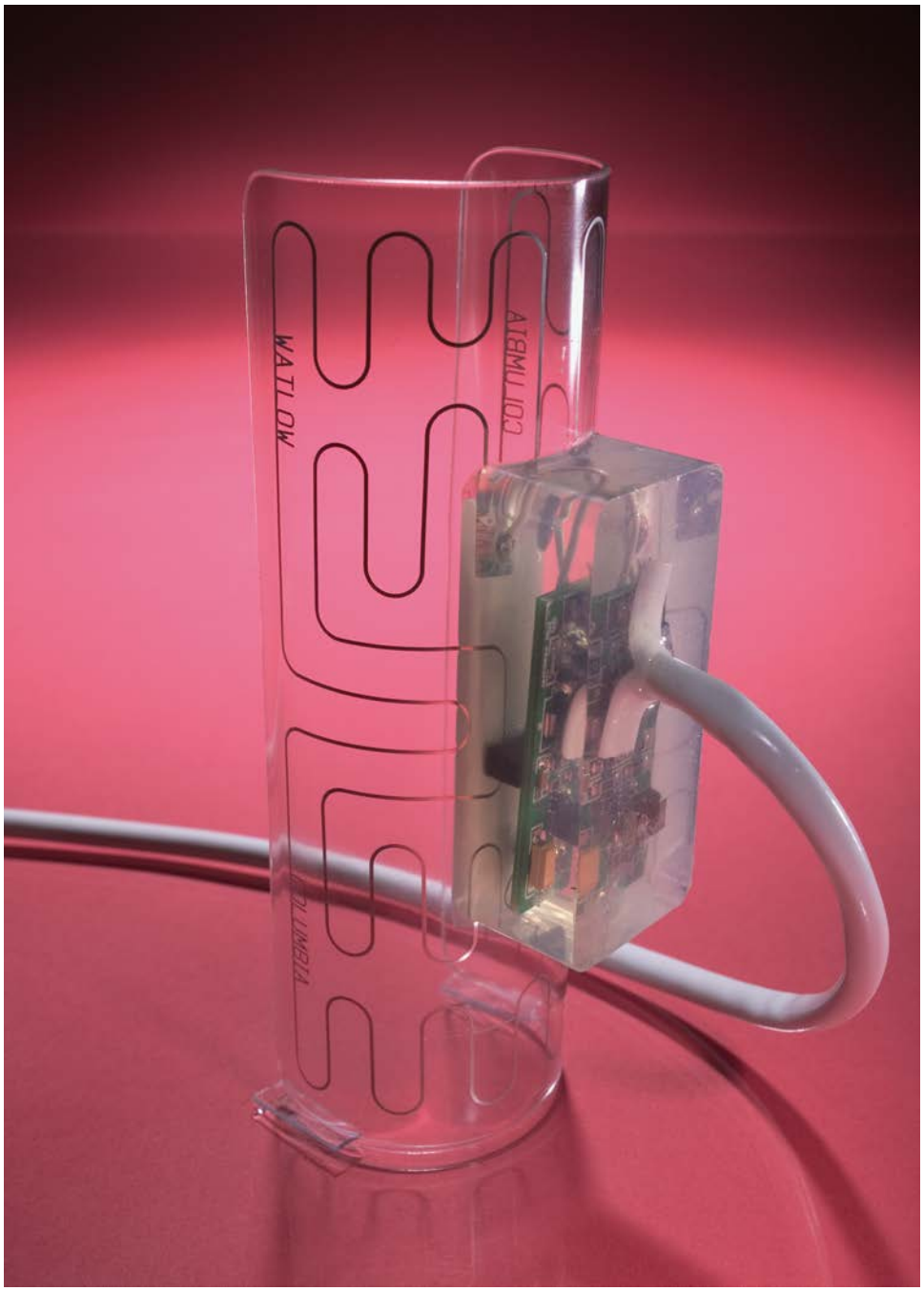
We are experiencing a dynamic period in medical device development, as new equipment and instrumentation is designed in order to administer new medical and pharmaceutical technologies. Additionally, new tests and instrumentation are developed to diagnose patient ailments. The broad scope of equipment function and design means there is not a single heater solution that will meet the performance requirements for thousands of types of equipment and processes.

The goal of all heater solutions is to supply the best performance for the medical device's intended use. Designing the best heater solution requires technical understanding of the thermal requirements and business understanding of how to best service the device manufacturer. Basic technical questions that a thermal engineer will ask a device engineer include:

- What is the application?
- Is the device heating air/gas, fluid or solid material?
- What is the process temperature?
- What is the temperature ramp rate?
- What are the dimensional requirements?
- Are there any known material compatibility issues?
- Are there any voltage limitations?
- Are there any special agency approval requirements?
- What is the heater life expediency?

Depending on the design requirements, a decision can be made as to whether the best thermal solution is convection, conduction, radiated or a combination of heat transfer methods. Convection heating is a mode of heat transfer in gas or liquid in which heat is transferred through movement of masses of the fluid from a region of higher temperature to one of lower temperature. Conduction heating is a mode of heat transfer within a body or between bodies that are in contact. Radiated heating is a mode of heat transfer where energy is emitted in the form of waves or particles.

A heater needs to be sized correctly for optimum performance. Dimensional requirements are usually governed by the allowable space in the device. Portability and space requirements of equipment are factors driving many of today's design decisions. For the heater designer, this usually means less space is available for the thermal solution and that drives design decisions toward an integrated solution rather than just a traditional heater component. For example, an integrated syringe heater assembly might include a foil heater element embedded in Lexan® (polycarbonate) housing, temperature sensors, temperature controller and a high limit controller in a compact reusable assembly that can be snapped on to a fluid delivery system.



Syringe Heater

Another example is a hematology analyzer thermal assembly in which a tubular heater is cast into an aluminum housing. The housing is treated with a nylon overcoat to allow for easy cleaning. The cast aluminum heater assembly assures a uniform temperature profile that is required for accurate and repeatable test results.

Hematology Analyzer Heater

Both applications require heating or maintain temperature of fluids to approximately 37°C (98.6°F). Sizing the heater for the optimum wattage requires knowledge of the flow rate, material being heated and needed change in temperature. The required wattage for a heater where there is a rise in temperature is calculated as:

kW= Liters/minute x Temperature Rise (°C)x 0.076

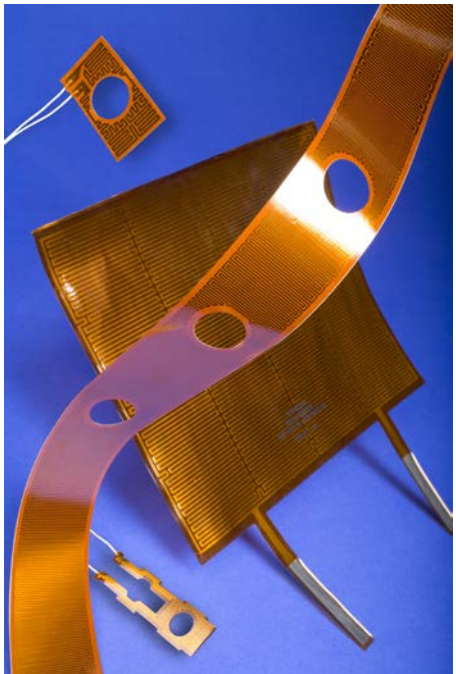
kW= Gallons/minute x Temperature Rise (°F)x 0.16

If the application is for air heating in applications such as a warming blanket or infant incubator, the heater wattage is calculated as:

kW = CFM x Temperature Rise (°F) / 3000 or
kW = Cubic Meters/minute · Temperature Rise (°C) / 47

Designing heaters for intend use is extremely important. Some application requirements are for 24/7 operation while others are disposable and intended for one-time usage. What both applications have in common is patient well being, including safety, comfort and performance results.

In respiratory therapy equipment, the heater(s) may be used to heat air, water for humidification and medication. The heaters are part of the base unit and expected to have years of reliable operation. Conversely, heaters used in colonoscopy procedures may be part of the point of use device and therefore disposable. While patient well being is critical in both applications, the robustness, long-term reliability and cost of the respiratory therapy heater will be different than the one-time use colonoscopy heater.



Polyimide flexible heaters

By understanding the product and agency requirements, there are many heater alternatives that simplify medical device design and procurement while reducing size and cost. A good example is meeting the safety requirements for low leakage current in medical devices. To summarize: U.S. leakage current deviation is based on the values and requirements of NFPA 99, “Health Care Facilities”

and the ANSI/AAMI “Safe Current Limits for Electromedical Apparatus” standards. The differences from IEC 60601-1 modify the acceptable passing limits for the earth and enclosure leakage tests, and maintain the same values for the patient leakage tests.

The base IEC 60601-1 standard does not directly differentiate between inside and outside the patient environment. IEC 60601-1-1, “Medical Electrical Systems,” which addresses a combination of several pieces of equipment, does make a distinction between inside the patient environment and outside it with respect to leakage current testing. UL® 60601-1 differentiates between patient-care equipment (6 ft around and 7.5 ft above the patient) and non-patient-care equipment for these leakage current tests. In UL® 60601-1, the leakage current values are specified in Tables 19.5DV.1 and 19.5DV.2. These values are given as:

- Class I product (typical value) = 300 µA patient-care area
- Class I product (typical value) = 500 µA non-patient-care area.

UL® 60601-1 allows opening of the ground conductor and one of the supply connections simultaneously for non-patient-care equipment. In most cases, the following is true: The earth leakage current test per UL® 60601-1 provides the worst-case conditions within the patient area, whereas the enclosure leakage current test per IEC 60601-1 is the worst-case test in the normal condition. Reference:
http://www.devicelink.com/mddi/archive/04/02/001.html

To meet these low current leakage safety requirements, many device manufacturers have resorted to using a step down isolation transformer and low voltage supply. The step down isolation transform adds significant cost, space and weight to the equipment. An alternative design approach would be to use a low current leakage heater that could eliminate the isolation transform and save cost and space. Advanced ceramic heaters with aluminum nitride (AlN) as a base material and a dielectric strength of >15KV/mm can be designed to meet the leakage current requirements. Medical equipment such as renal dialysis, insufflators, lithotripters and thermal abrasion could benefit from the performance and cost benefits of AlN heaters.

ULTRAMIC® Advanced Ceramic Heaters

When choosing the right heater partner, there are several criteria that should be considered. Is the supplier capable of providing timely design and prototype support? Does the heater supplier have more than one technology solution so that the best solution can be provided? Can the heater supplier provide global logistical support? Will the entire design and business relationship provide the best solution for the device manufacturer?

As new discoveries are made and equipment developed, temperature is expected to play an important role. Detailed study of the human genome would be virtually impossible without precision temperature control. Patient healing and recovery can be accelerated by optimizing temperature. Long-term patient care and comfort are enhanced by managing the temperature of treatments. Subsequently, medical device and instrumentation designers are including heaters with new functionally in their next generation of products.

Royce Payton has 28 years of experience at Watlow, holding several technical roles involving design, testing and applications engineering of thermal systems. Payton majored in Mechanical Engineering at Washington University in St. Louis. He currently leads the business development activities for the flexible heater line of business which includes the responsibility for account management, design/technical support and product management.