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SAFETY BRIEF

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On the Safety of Heating Pads

by Ralph L. Barnett and James R. Wingfield

ABSTRACT

The electric heating pad represents one of the medical devices that escaped the FDA safety net by a "grandfather" exemption. An amazing number of philosophical safety issues are introduced by this relatively innocuous commodity. Pain relief is a major attribute of heating pads followed by a minor in actual medical efficacy associated with the improvement of local blood circulation. By contrast, the historic downside is very dramatic featuring electrocution, fire, and skin burns. This paper begins with a brief introduction to current protocol for placing new medical devices into the stream of commerce. In the case of heating pads, it is fortunate that the Underwriters Laboratories Inc. developed and promulgated design rules that effectively mitigated the dangers of shock/electrocution and fire. On the other hand, UL has not undertaken a technical program that addresses the skin burn problem that is the focus of this paper. Nevertheless, many heating pad manufacturers are under the impression that their compliance with UL 130 has ameliorated the skin burn propensity of their pads. Heating pad manufacturers have attempted to control skin burn injuries exclusively through the means of on-product and in-manual warnings that have been promulgated by UL, FDA, and CPSC. This approach has tenaciously maintained a burn rate of 1600 cases per year. A different approach to the skin burn problem is automatically orchestrated by invoking the "Safety Hierarchy." For example, falling asleep and causing prolonged skin exposures to a heated pad can be eliminated by a dead-man control. Exposure to extreme temperatures that arise when both faces of the pad are concurrently covered is perhaps the most prevalent cause of skin burns. This paper exploits the notion of monitoring both face temperatures and shutting off the pad when they are almost the same. We also explored shutting down the pad when the cycle rate of the bang-bang controls was sufficiently slow; higher heating rates are associated with an uncovered face.

INTRODUCTION

The safety of the ubiquitous electric heating pad has been the preoccupation of the UL130 Standard for Electric Heating Pads, which was first published in 1933 by Underwriters Laboratories, Inc. The latest edition of UL 130, the thirteenth, was published July 15, 2011 and contains sixty two pages including revisions through October 14, 2011 [1]. Almost every electric heating pad manufacturer embraces the UL safety technology; most are UL Listed.

A. Underwriters Laboratory, Inc.

The UL 130 standard identifies three pad failure modes; fire, electric shock, and skin burns. The historic strength of UL in the first two areas, fire and shock, is manifest throughout UL 130 where interventions are fully developed in the form of specifications, suggestions, requirements, and test protocols. Indeed, accident statistics reflect the efficacy of the standard; less than eight death cases a year are caused by fires associated with electric heating pads. The Consumer Product Safety Commission (CPSC) [2] estimates that most of the yearly 1600 electric heating pad accidents treated in hospital emergency rooms are caused by thermal burns not caused by fire.

To ameliorate the danger of skin burns, the UL has invoked a warnings program under the appellation "Markings." Specifically, the following six warnings listed in Table I constitute the singular attack on the problem:

The UL 130 standard reflects no medical, biological, epidemiological, or technical studies on skin burn. Furthermore, based on testimony of a principal UL engineer [3], the Thirteenth Edition has no skin burn input from CPSC, the Food and Drug Administration (FDA), or any other government agencies.

Clearly, for preventing skin burns, the contact temperatures between the skin and the cloth cover are the most important temperatures. The maximum allowable contact temperatures are not specified in UL 130 for preventing or mitigating skin burns. On the other hand, the maximum allowable temperatures on the vinyl surfaces are described in the Heating Test section of the standard without reference to skin burns or any rationale [1]. For

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Table 1. UL Skin Burn Warnings

1. DO NOT USE WHILE SLEEPING.
2. DO NOT USE ON AN INFANT.
3. THIS PAD IS NOT TO BE USED BY OR ON AN INVALID, SLEEPING OR UNCONSCIOUS PERSON, OR A PERSON WITH POOR BLOOD CIRCULATION UNLESS CAREFULLY ATTENDED.
4. DO NOT USE ON AREAS OF INSENSITIVE SKIN.
5. BURNS CAN OCCUR REGARDLESS OF CONTROL SETTING, CHECK SKIN UNDER PAD FREQUENTLY.
6. NEVER USE PAD WITHOUT COVER IN PLACE (hospital pads if provided with cover and all household pads).

example, for heating pads that are fully sandwiched between one inch thick felt pads that are heated to steady state temperatures, the maximum allowable vinyl surface temperatures are specified as 90° C [194° F] for household pads and 55° C [131° F] for hospital pads. To put these temperatures in perspective, indefinite exposure without burn damage only occurs below 104° F [4].

The statistical evidence indicates that the UL warnings approach does not provide sufficient control over skin burns; so what? UL is not a government agency, it has no mandate to address this hazard, and it does not herald skin burns as a cause célèbre. The answer to the 'so what' question lies with the electric heating pad manufacturers. When they get sued for causing skin burns they use UL 130 compliance as a defense. This is further illustrated by the following excerpts from a leading pad manufacturer's manual:

"Commonly Asked Questions

Q. How fast should my heating pad heat-up?
A. Your heating pad is specially designed for the fastest heat-up allowed by the national recognized independent best laboratory that the electronics industry relies on for safety testing. Your heating pad should reach the high temperature setting in less than 10 minutes.

Q. My heating pad doesn't feel hot enough?
A. Your heating pad is specially designed for the highest heat allowed by the national recognized independent best laboratory that the electronics industry relies on for safety testing."

B. FDA/CPSC

On December 12, 1995, the FDA and the CPSC issued a Public Health Advisory [2] on the hazards associated with the use of electric heating pads. They estimated the annual carnage in nursing homes, hospitals, and homes as eight deaths and 1600 skin burns. Their analysis of the accident reports gave rise to the conclusion "In most cases, they could have been avoided by careful inspection and proper use of the heating pad." It should be noted that this conclusion applies to almost every accident that ever occurred with any artifact created by man. The response of the FDA/CPSC to the problem of heating pad safety is a "warnings" program. Their explicit Advisory warnings are listed in Table 2. In addition, the text of the Advisory restricts the use of pads to people who may be unable to feel skin pain; they are listed in Table 3.

Finally, the Advisory points out that "Prolonged use on one area of the body can cause a severe burn even when the heating pad is at a low temperature setting [also see Table 1, item 5]."

The Advisory does not call for or recommend design or protocol changes of any kind; e.g., lower maximum exterior temperature, deadman controls, curtailed treatment time, and heavier removable covers.

C. Accident Frequency

The UL, FDA, and CPSC have chosen to treat electric heating pad skin burns exclusively by on-product and in-manual warnings. In the opinion of the authors this approach is both cavalier and unacceptable. From 1995 through 2008 pad manufacturers have included with their products an average of two dozen different warnings that appear multiple times in various languages. Unfortunately, the CPSC estimates that annual skin burns increased by 33.9% from 1600 in 1995 to 2142 in 2008 [5].

D. Food and Drug Administration

The electric heating pad is a medical device. It is an over-the-counter product which the Food and Drug Administration (FDA) has classified as a Class II device.

The FDA began with the Food and Drug Act of 1906 at a time when medical devices were not prominent in the practice of medicine. Over the next seventy years this changed significantly which resulted in the Medical Device Amendments of 1976. Along with the original FDA charter which was to assure the safety and efficacy of drugs, this same requirement was imposed on medical devices which were defined by the FDA as follows:

The term "device" means: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes

Table 2. FDA/CPSC Electric Heating Pad Warnings

ALWAYS –

7. Inspect heating pad before each use to assure it is in proper working order; discard it if it looks worn or cracked or if the electrical cord is frayed.
8. Keep removable cover on pad during use.
9. Place heating pad on top of, and not underneath of, the body part in need of heat. (The temperature of a heating pad increases if heat is trapped.)
10. Unplug heating pad when not in use.
11. Read and follow all manufacturer's instructions on heating pad or on outside package prior to use.

NEVER –

12. Use on an infant.
13. Use on a person who is paralyzed or has skin that is not sensitive to temperature changes.
14. Use on a sleeping or unconscious person.
15. Use in an oxygen enriched environment or near equipment that stores or emits oxygen.
16. Sit on or against a heating pad.
17. Crush or fold a heating pad during use or during storage.
18. Unplug heating pad by pulling its connecting cord.
19. Use pins or other metallic fasteners to hold heating pad in place.

Table 3. Restricted Community of Pad Users (FDA/CPSC)

20. Advanced Age
21. Diabetes
22. Spinal Cord Injury
23. Drinking Alcohol
24. Medication for Pain or Sleeplessness
25. Stroke

through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Good manufacturing practices (GMP), required for drug manufacturers, were now also required for device manufacturers. Examples of GMP applied to medical device manufacturers includes but is not limited to:

- vendor selection/qualification and control
- comprehensive quality control
- good laboratory practices (GLP)
- qualified technical staff
- customer complaint reporting investigation and resolution
- application of current codes and standards

By 1976 there were already many medical devices in the market place which had not been through the formal product review process made necessary by the new amendments. Many of these devices would continue to be manufactured in one form or another as post-amendment devices.

Due to the evolutionary nature of the medical profession, new devices and device technology were also evolving which were clearly under the scope of the new regulations.

In order to establish a coherent system of risk management, all medical devices were divided into three classes according to the perceived risk associated with their design objective and biological effect on the patient/user. The level of control required to address safety and efficacy in each class was then assigned in idiomatic terms which manufacturers were expected to make specific to each product they listed with the FDA. The specifics here were commonly understood to be a collection of practices to eliminate or control the risks which were inherent in the application or technology of the medical device.

The FDA assigns all medical devices to one of three classes. This includes both pre-amendment and post-amendment devices. It is understood in the industry that the assignment rules often do not appear to follow the same logic. For example; surgeons gloves are Class I and a surgical mask is Class II. The FDA can also reassign a device to a different Class if it comes up for review.

These categories reflect the basic premise of the FDA that all medical products must be safe and effective to qualify for use on humans. All risks must be absent or well understood and weighed with respect to outcome benefits.

The three medical device classes by increasing risk are:

Class I – (insignificant risk) requires:
- general controls

Class II – (moderate risk) requires:
- general controls
- special controls

Class III – (significant risk) requires:
- general controls
- special controls
- pre market approval

General Controls apply to all classes uniformly. A partial list includes:

1. Registration with the FDA of all manufacturing facilities.
2. All medical devices must be listed with the FDA.
3. All new and modified devices require prior notification.
4. Manufacturers must follow Good Manufacturing Practices (GMP).

Special Controls extend beyond general controls by addressing the specific device technology: Identification of critical components, special calibration requirements, EMI susceptibility, fault simulation testing as may be required to assure that inherent failure modes are anticipated and protected by state-of-the-art countermeasures. This can include, but is not limited to the type of testing performed by Underwriters Laboratories for protecting against fire and electric shock risks.

Pre Market Approval is an additional requirement for Class III medical devices. Class III devices pose the highest potential risk of adverse reaction consequences. The FDA wants assurance from the manufacturer that the risks are fully evaluated by protocol driven studies conducted by medical professionals which usually requires clinical trials with human subjects.

The distinguishing feature of the Class II heating pad is that it is electric and rated for 50-55 watts of power consumption. All electric devices are capable of fire or shock hazards at minimum. But these are not intrusive biological hazards which would automatically put the heating pad into Class III requiring pre market clinical testing.

As a Class II device, heating pads would require only general controls (such as GMP) and special controls which could be argued to be satisfied by UL 130 testing. However, biological hazards such as tissue reactivity to thermal exposure are not addressed by UL 130, especially in this case where thermal exposure is the intended performance objective.

For the purpose of discussion assume that the electric heating pad is a new post amendment device with no predicate history. The manufacturer can not apply for pre market approval as a Class II device using the 510 (k) exemption to establish safety and efficacy. The design basis alone calls for the conversion of electrical energy into heat energy which is transferred into the body by contact with the skin. The obvious risk factors are electric shock, fire and thermal burns which are biological.

Independent of this particular device, the FDA had concluded that controls for the biological evaluation of medical devices should be supplemented using an amplified version of the international standard ISO 10993 "Biological Evaluation of Medical Devices," Table 4.[6]

Using the guidelines given in this table in application to heating pad devices we note that under body contact for less than 24 hours, evaluation for "intra cutaneous reactivity" is recommended. This would certainly require protocol driven testing under clinical conditions. We do not presume that such protocol driven testing would be a trivial matter but it is a rational approach to setting design limits for safe use.

The ISO 10993 table clearly includes the kind of biological effect which is inherent in the use of heating pads, and the ISO evaluation test considerations are clearly not included in the UL 130 standard which is the only "special controls" evaluation method used by heating pad manufacturers.

WARNINGS

The response of UL, FDA, and CPSC to the skin burn problem has been an on-product and in-manual warnings attack. This approach is blunted by a significant onslaught of warnings that are needed to address fire and shock safety which, together with skin burns, constitute the three major electric heating pad hazards. Minor, but ever-present dangers, such as tripping, suffocation, and strangulation, are not considered.

Manufacturers have embraced the inexpensive warnings approach to skin burns by compiling a list of contra-indications for use and adverse reactions that now appear on the product. These include the UL warnings listed in Table 1 which give the on-product warnings the imprimatur of compliance with standards. All of the FDA/CPSC warnings contained in Tables 2 and 3 are also included with a typical heating pad. In addition, manufacturers have developed and displayed many caution signs that are all collected in Table 5.

Most of the exhortations presented in Tables 1, 2, 3 and 5 are characterized by a lack of artfulness in their formulation. When presented en masse, the set of warnings is mind-boggling. For example, Table 6 is a partial collection of warnings taken from one manufacturer; it embodies almost every negative attribute of an on-product warning. We have had occasion to redeploy this set of warnings into strategic groups such as found on ladder warning labels; however, the intrinsic communication problem is ever present. Forty-plus is just too many warnings to provide an effective safety program.

SAFEGUARDING ELECTRIC HEATING PADS

Unfortunately, without user training, the army of heating pad warnings marshaled to protect against skin burns are not adequate. Most skin burn accidents can be attributed to three reasonably foreseeable misuses of the pads;

1. Covering both faces of the pad. This increases the contact temperature.

2. Falling asleep during use. This increases the exposure time.

3. Omitting the cloth cover. This increases the contact temperature and the transfer rate of heat energy.

An appeal to basic safety philosophy suggests that the Safety Hierarchy will provide a more promising approach to the problem than warnings. [7]

Table 4. Biological Evaluation of Medical Devices

Device categories			Biological effect							
Body contact		Contact duration A - limited (less than 24 hours) B - prolonged (24 hrs to 30 days) C - permanent (more than 30 days	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	System toxicity (Acute)	Subchronic toxicity (subacute toxicity)	Genotoxicity	Implantation	Hemocompatibility
Surface devices	Skin	A	x	x	x					
		B	x	x	x					
		C	x	x	x					
	Mucosal membrane	A	x	x	x					
		B	x	x	x	o	o		o	
		C	x	x	x	o	x	x	o	
	Breached or compromised surfaces	A	x	x	x	o				
		B	x	x	x	o	o		o	
		C	x	x	x	o	x	x	o	
External communicating devices	Blood path, indirect	A	x	x	x	x				x
		B	x	x	x	x	o			x
		C	x	x	o	x	x	x	o	x
	Tissue/bone/ dentin communicating+	A	x	x	x	o				
		B	x	x	o	o	o	x	x	
		C	x	x	o	o	o	x	x	
	Circulating blood	A	x	x	x	x		o ^	x	x
		B	x	x	x	x	o	x	o	x
		C	x	x	x	x	x	x	o	x
Implant devices	Tissue/bone	A	x	x	x	o				
		B	x	x	o	o	o	x	x	
		C	x	x	o	o	o	x	x	
	Blood	A	x	x	x	x			x	x
		B	x	x	x	x	o	x	x	x
		C	x	x	x	x	x	x	x	x

x = ISO evaluation tests for consideration o = Additonal tests which may be applicable
NOTE + tissue includes tissue fluids and subcutaneous spaces
NOTE ^ For all devices used in extracorporial circuits
[By permission: Whitmore, Elaine, "Product Development Planning for Health Care Products Regulated by the FDA," ASQC Quality Printing, 1997.]

Since the early 1950s, safety organizations have been developing a safety hierarchy to guide designers in the philosophical approach to safe product development. By 1985, the development had stabilized and most countries had adopted the version presented in Table 7.

Observe in Table 7 that Warnings are adopted after the designer attempts to eliminate the danger and safeguard the danger. If the first and second priorities are not feasible and practicable, then the designer resorts to warnings.

The First Priority, eliminating the dangers associated with electric heating pads, is an example of alternate design theory which presently embraces generalizations of the hot water bottle, exothermic chemical pads, or hot rocks in a bag (e.g. microwaving a gel pack). These products preserve the function of the electric heating pad while losing its ubiquitous and inexhaustible power source. This is not the case when the Second Priority is applied to safeguard the pad.

A. Heating Pad Cover

The Caution, "Keep removable cover on pad during use," has been eliminated by Sunbeam® on their Model 2013-912 heating pad. This model uses a permanent cover and carries a five-year warranty.

B. Dead-Man Control

The classic deadman control originally placed in locomotives to prevent runaway trains caused by incapacitated motormen is a perfect example of a safeguarding concept that can protect users who fall asleep with an operating heating pad. Figure 1 is a photograph of a circa 1977 Thermophore® heating pad which illustrates a woman in prone position with her thumb on a lever that must be continuously depressed to maintain operation of the pad. Figure 2 characterizes the deadman control. The Thermophore® safety philosophy is contained in the Safety paragraph printed on their packaging; "Safety: The Battle Creek THER-

Table 5. Warnings Developed by Pad Manufacturers

26. This appliance has a polarized plug (one blade is wider than the other). As a safety feature, this plug will fit in a polarized outlet only one way. If the plug does not fit fully in the outlet, reverse the plug. If it still does not fit, contact a qualified electrician. Do not attempt to defeat this safety feature.
27. Do not use an electrical outlet that has become loose or does not engage the power plug tightly.
28. Do not immerse in water or use chemicals or solvents during cleaning, except as directed in the owner's manual.
29. Do not remove product labels that contain warnings or safety instructions.
30. Save these instructions.
31. For Indoor Household Use Only.
32. Do not lie on top of the heating pad. Never place pad between yourself and chair, sofa, bed or pillow.
33. Carefully examine inner cover before each use. Discard the pad if inner covering shows any sign of deterioration.
34. Loop cord loosely when storing. Tight wrapping may damage cord and internal parts.
35. Do not use pad with liniment, salve or ointment preparations that contain heat-producing ingredients. Skin burns can result.
36. Do not use a heating pad when symptoms of appendicitis are present, consult your physician.
37. Do not use if voltage exceeds 125 V.
38. Pad must lay flat inside cover.
39. Do not use on persons with nerve damage.
40. Do not use on persons with Rheumatoid arthritis.
41. Do not use the cord as a handle.
42. Never leave this appliance unattended, especially if children are present.
43. Do not use on an animal.
44. Never unplug pad from electrical outlet with a wet hand.
45. If using an extension cord with this pad, the marked electrical rating of the cord set/extension cord should be as great as electrical rating of the pad.

MOPHORE has been certified to be safe by an independent electrical testing laboratory. People who use the THERMOPHORE find the treatment so soothing that each unit is equipped with a safety switch which shuts off automatically, should you fall asleep during a THERMOPHORE treatment."

A subsequent model of the Thermophore® uses an on/off switch with a maximum heating time of 20 minutes instead of a deadman control. Their manual states, "You can restart the 20-minute timer any time by pushing the green "On" button, or end the session by pushing the red "Off" button. If you happen to doze off or just forget to press the "Off" button, the built-in-timer will automatically shut the unit off for safety." This later model pad resists attempts to bypass the dead-man control by "tying down the lever."

Table 6. Typical Set: On-Product Warnings

DANGER

TO REDUCE THE RISK OF BURNS, ELECTRIC SHOCK, AND FIRE, THIS PRODUCT MUST BE USED IN ACCORDANCE WITH THE FOLLOWING INSTRUCTIONS: •BURNS CAN OCCUR REGARDLESS OF CONTROL SETTING, CHECK SKIN UNDER PAD FREQUENTLY. •DO NOT SIT ON, LEAN AGAINST, OR CRUSH PAD – AVOID SHARP FOLDS, ALWAYS PLACE PAD ON TOP OF AND NOT UNDER YOUR BODY. NEVER PLACE PAD BETWEEN YOURSELF AND CHAIR, SOFA, BED, OR PILLOW. •DO NOT USE WHILE SLEEPING. •DO NOT USE ON AN INFANT. •THIS PAD IS NOT TO BE USED ON OR BY AN INVALID, SLEEPING OR UNCONSCIOUS PERSON, OR A PERSON WITH POOR BLOOD CIRCULATION OR DIABETES UNLESS CAREFULLY ATTENDED. •DO NOT USE ON AREAS OF INSENSITIVE SKIN. •NEVER USE PAD WITHOUT THE CLOTH COVER IN PLACE. DO NOT USE PINS OR OTHER METALLIC MEANS TO FASTEN THIS PAD IN PLACE. •DO NOT USE IN OXYGEN ATMOSPHERE. •NEVER PULL THIS PAD BY THE POWER SUPPLY CORD. DO NOT USE THE POWER SUPPLY CORD AS A HANDLE. UNPLUG WHEN NOT IN USE. •DO NOT USE PAD WITH LINIMENT, SALVE, OR OINTMENT PREPARATIONS THAT CONTAIN HEAT-PRODUCING INGREDIENTS. SKIN BURNS COULD RESULT. •CAREFULLY EXAMINE INNER COVER BEFORE EACH USE. DISCARD THE PAD IF INNER COVER SHOWS ANY SIGN OF DETERIORATION. •READ AND FOLLOW ALL INSTRUCTIONS ON BOX OR PACKED WITH PAD BEFORE USING.

Table 7. Safety Hierarchy, 1985

First Priority	Eliminate the hazard and/or risk
Second Priority	Apply safeguarding technology
Third Priority	Use Warning Signs
Fourth Priority	Train and Instruct
Fifth Priority	Prescribe Personal Protection

C. Double Thermocouples

Covering both sides of a pad during therapy causes the temperature and heat transfer at the interface between the heating pad and the body to increase to dangerous levels. There are eight warnings in Tables 2 and 5 which address this misuse. It is our opinion that this misuse should be eliminated by design rather than mitigated by warnings.

Figure 1 Thermophore® Heating Pad

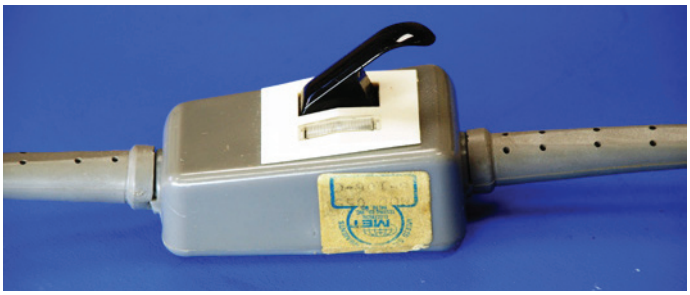


Figure 2 Deadman Control

1. Experimental Method

The heating pad is a symmetrical heat generator when both sides are open to atmosphere (room temperature). The same quantity of heat is transferred from each side because the temperature on each side is equal. In use, however, this is not the case since the body's core temperature tends to be warmer than the ambient air (72°F). The (98,6ºF) result is an asymmetrical heat transfer.

Using the "breadboard" components illustrated in Figure 3, a Model HP-110 heating pad manufactured by KAZ, Inc. (Figure 3a) was tested for 120 minutes with the Hi control setting. This pad was retrofitted by placing a K-type thermocouple (Figure 3b) at the geometric center of both vinyl faces. This instrumented pad was placed into the cloth sleeve (Figure 3c) provided by KAZ. The test was conducted by placing the test pad on top of an application surface that roughly approximated the behavior of a human body. This application surface consisted of a second heating pad set on Lo (Figure 3d). The temperature of this surface was measured to be 88°F, about 6°F cooler than a human body surface temperature of 94°F.

The thermocouple temperature on the test pad in contact with the application surface was designated T_1; The Top Side thermocouple temperature was T_2. With the test pad set on Hi, the temperatures T_1 and T_2 were monitored for 60 minutes; the values are tabulated in Table 8 where each data point represents the average of ten readings. At the end of this 60 minute interval, the Top Side of the test pad was insulated by placing a 1/2 inch thick felt pad (Figure 3e) over the exposed surface where it remained for 60 minutes until completion of the two hour test run. The temperatures T_1 and T_2 associated with this insulated phase of the testing program are displayed in Table 9. Once again each data point represents the average of ten readings. The PLC shown in Figure 3f was programmed to accept two kinds of data generated by the test,

1. K Thermocouple millivoltage currant – two channels
2. The thermostat duty cycles in terms of t_{on} and t_{off}

The converted temperatures from each of the two thermocouples was reported every five minutes as an average of ten digitized samples automatically computed in the PLC program.

2. Preliminary Results

The initial overshoot of temperature shown in Fig. 4 is a typical response from the on-off control action found in a thermostatic device. It is especially pronounced when the design objective is to bring the heating pad up to operating temperature as quickly as possible.

The test data presented in Tables 8 and 9 confirm that covering the open side tends to drive the open side temperature T_1 closer to T_2 as shown in Figure 4. Using this difference as a diagnostic it was spliced into the program logic as a decision gate which was used to send a control signal to the power input which could override the operation of the heating pad.

Although the metric we use to illustrate this principle is temperature, decisions are made on differences of thermocouple outputs in millivolts. We avoid any conjecture about the temperatures and relationships to the biological effects. The viability of this diagnostic was demonstrated to our satisfaction at the bench test level.

The results of the testing program are summarized in Figure 4. The following observations are noteworthy:

a. Top Side Open to Atmosphere

i. The start-up temperature was 72°F.

ii. In the first 10 minutes the Body Side temperature T_1 overshoots to about 150°F before returning to a steady state temperature of 138°F.

iii. T_1 remained steady at 138° for about 50 minutes.

iv. The Top Side temperature T_2 exhibits a similar response, overshoots to about 130°F and returns to a steady state of about 118°F for the next 40 minutes.

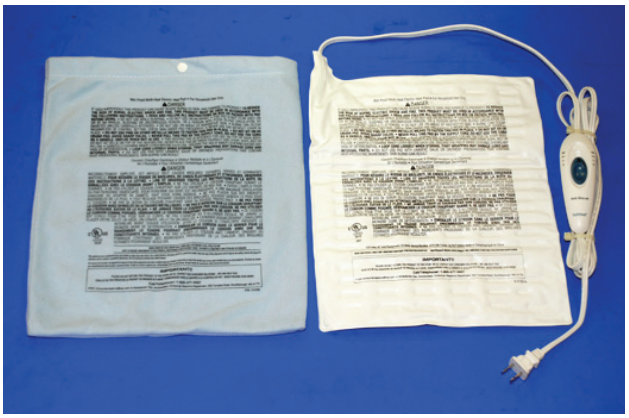
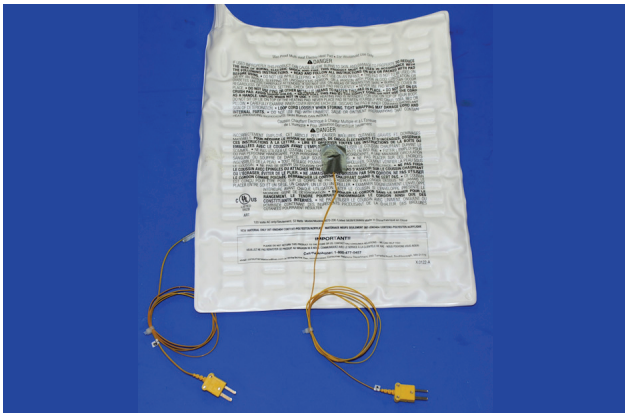


Figure 3a – Test Pad, Model HP-110, KAZ, Inc.

3d – Application Surface – Heating Pad Set at Lo (88°)



3b – Test Pad with Thermocouples
Retrofitted on Both Faces

3e – Felt Pad Insulator (1/2 in. thick)

3c – Removable Cloth Cover

3f – PLC

Figure 3 - Breadboard Model Components

Table 8. Normal Heating Pad Operation
Top Side Open to Atmosphere
(Each data point is the average of ten readings)

	Body Side	Top Side
Time (min.)	T_1(°F)	T_2(°F)
0	72.9	72.8
5	142.0	130.7
10	150.9	127.6
15	142.1	122.1
20	140.0	121.2
25	139.4	120.9
30	138.9	119.6
35	139.0	119.4
40	138.8	180.0
45	139.1	119.7
50	139.2	120.0
55	138.6	119.4

Table 9. Heating Pad Operations with
Top Side Insulated
(Each data point is the average of ten readings)

	Body Side	Top Side
Time (min.)	T_1(°F)	T_2(°F)
60	139.4	121.2
65	140.0	126.5
70	141.3	132.4
75	142.4	132.6
80	141.6	136.4
85	141.9	137.6
90	141.8	138.3
95	141.6	138.2
100	141.4	138.2
105	141.4	139.7
110	141.3	138.1
115	141.1	138.1
120	142.3	139.1

v. The programmable logic controller (PLC) shown in Figure 5f recorded a steady state temperature difference (T_1-T_2) of 20°F when the test pad had its Top Side open to the atmosphere (mfg's. recommendation).

b. Top Side Insulated

i. After 60 minutes the Top Side of the test pad was insulated with a felt pad.

ii. Over the next 15 minutes the Body Side temperature T_1 rose from 138°F to 142°F.

iii. Within 15 minutes the Top Side temperature T_2 rose from 118°F to 136°F.

iv. Over the next 40 minutes T_1 is stable and T_2 gradually increases to within 5° to 6°F of T_1.

v. The PLC recorded that the initial steady state difference (T_1-T_2) of 20°F becomes a 6°F difference in 15 minutes. This change in (T_1-T_2) reflects the physical application of an insulated cover of the Top Side. This manifestation causes the PLC to shut off the heating pad to protect the user from this "covering misuse."

vi. Note that the two thermocouples can also serve as an additional layer of protection. At a preset temperature level the PLC can shut off the heating pad as an emergency measure.

D. Duty Cycle Control

It takes more energy to maintain a steady state heating pad temperature when one face of the pad is uncovered because some energy is expended in heating the environment. Consequently, the on/off electrical demand spends more time in the "on" state when a pad face is uncovered as opposed to covered.

If the average heating times are stable and significantly different in the covered and uncovered states, a small difference in the average heating time provides a criterion for shutting off the heating pad before skin burns occur. This duty cycle concept has great potential. No additional hardware, thermocouples, or wiring are required. Only control logic and monitoring activities are incorporated to provide a primary or secondary safety system.

1. Test Program

The PLC was programmed (Figure 3f) to measure the period of an on/off cycle after preliminary testing indicated this was a factor common to the thermostatically controlled power input. This is the most elementary method of control as contrasted with proportional controllers.

The cycle period τ of this type of control is the sum of time ON plus time OFF, thus:

$$\tau = t_{on} + t_{off} \qquad \text{(Eq.1)}$$

This is a stochastic variable; the average of ten cycles was used to describe this period. Using this cycle period a ratio $\overline{R}_{off}$ was then defined as:

$$\overline{R}_{off} = \frac{\overline{t}_{off}}{\overline{t}_{on} + \overline{t}_{off}} = \frac{\overline{t}_{off}}{\overline{\tau}} \qquad \text{(Eq. 2)}$$

where the overbar symbol denotes an average.

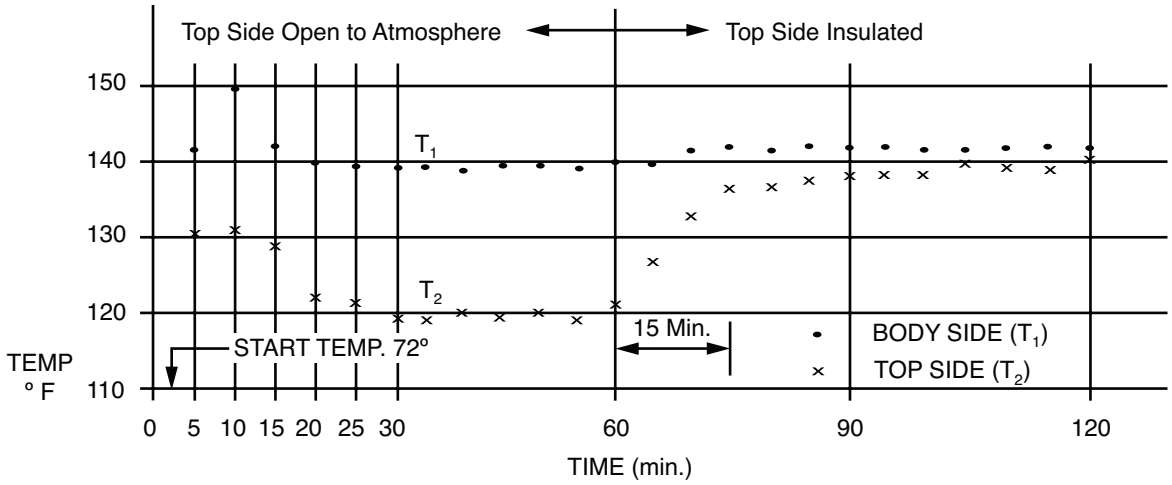


Figure 4 - Temperature vs Time Data - Controls set on III (HI)
(Each data point is the average of ten readings)

Using the same "breadboard" set up previously adopted to study temperatures, a two hour test run was undertaken to study the duty cycles of an uncovered and an insulated heating pad. The test protocol is characterized as follows:

i. With the test pad set on Hi, place the pad onto the 88°F application surface (Figure 3d)

ii. For various 5 minute intervals measure ten values of t_{on} and t_{off} with the Top Side of the test pad open to the atmosphere.

iii. Repeat (ii) after insulating the Top Side with the felt pad shown in Figure 3e.

iv. Remove the insulation and after a delay continue (ii).

The duty cycle data is tabulated in Table 10. The mean value of the seven averages for $\overline{R}_{off}$ associated with the uncovered test pad is

$$\text{Mean } \overline{R}_{off} = 0.6230\ldots\text{Uncovered} \qquad \text{(Eq. 3)}$$

The corresponding mean of seven averages $\overline{R}_{off}$ for the covered test pad is

$$\text{Mean } \overline{R}_{off} = 0.7029\ldots\text{Covered (Insulated)} \qquad \text{(Eq. 4)}$$

2. Preliminary Results

In our quest to find safeguarding methods that will ensure one face of an electric pad will remain open to the atmosphere during therapy, the notion emerged that duty cycle might furnish a "detection criterion." The duty cycle of a pad is caused by the presence of internal micro-thermostats that are preset to open and close at a fixed temperature. Our testing program was highlighted as follows:

i. A hypothesis was formulated that the heating phase of the duty cycle will remain inoperative for a shorter time period when the Top Side is uncovered relative to its insulated performance.

ii. The hypothesis was supported by comparing 70 duty cycle readings for each of the covered and uncovered states, i.e., [Covered $\overline{R}_{off}$ - Uncovered $\overline{R}_{off}$] = 0.0799. The inactive time t_{off} increased 12.83% when the Top Side was covered.

iii. Can the difference in $\overline{R}_{off}$ ratios between the covered and uncovered states be used as a "detection criterion" for establishing that the Top Side is covered or insulated? This possibility is far from settled. The $\overline{R}_{off}$ differences are small. They have not been studied for various control settings or application scenarios. Stability and robustness remain unknown properties.

iv. If the detection criterion, [Covered $\overline{R}_{off}$- Uncovered $\overline{R}_{off}$] > 0 can be established as a reliable detection algorithm it has great appeal. The mechanisms which generate this data are already contained in the pad and the incorporation of software decision logic into a small microprocessor located in the control switch is feasible.

CONCLUDING COMMENTS

The set of forty-four on-product and in-manual warnings associated with electric heating pads plays an insignificant role in safety and a major role in liability proofing especially with respect to skin burns. An application of the Safety Hierarchy de-emphasizes the warnings attack on the skin burn problem and substitutes a safeguarding approach that we apply to two major misuses; falling asleep and covering both faces of the pad during therapy.

Table 10. Duty Cycles (Each date entry for $\bar{t}_{on}$ and $\bar{t}_{off}$ is the average of ten readings)

Run Time (min.)	$\bar{t}_{on}$	$\bar{t}_{off}$	$\overline{R}_{off}$	Cover
5-10	6.9	13.8	0.666	Off
10-15	9.5	15.3	0.610	Off
15-20	10.6	16.9	0.614	Off
20-25	12.5	20.3	0.618	Off
25-30	16.1	23.4	0.592	Off
60-65	16.5	24.9	0.600	On
65-70	15.7	31.0	0.664	On
70-75	17.0	40.2	0.702	On
75-80	14.7	39.9	0.730	On
85-90	16.6	40.0	0.709	On
90-95	17.0	47.9	0.738	On
95-100	15.1	52.8	0.777	On
110-115	18.6	33.7	0.644	Off
115-120	21.5	35.0	0.619	Off

The third most important area of misuse involves the screening of the population for unsuitable heating pad candidates. This is not a viable mitigation strategy; it relies heavily on frequent skin checks under the pad which often require an attendant. It is axiomatic in the heating pad industry that absolute skin burn safety is not achievable even with perfect fidelity to the warnings. The safety issue is entirely about minimizing the number of accidents and their severity.

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