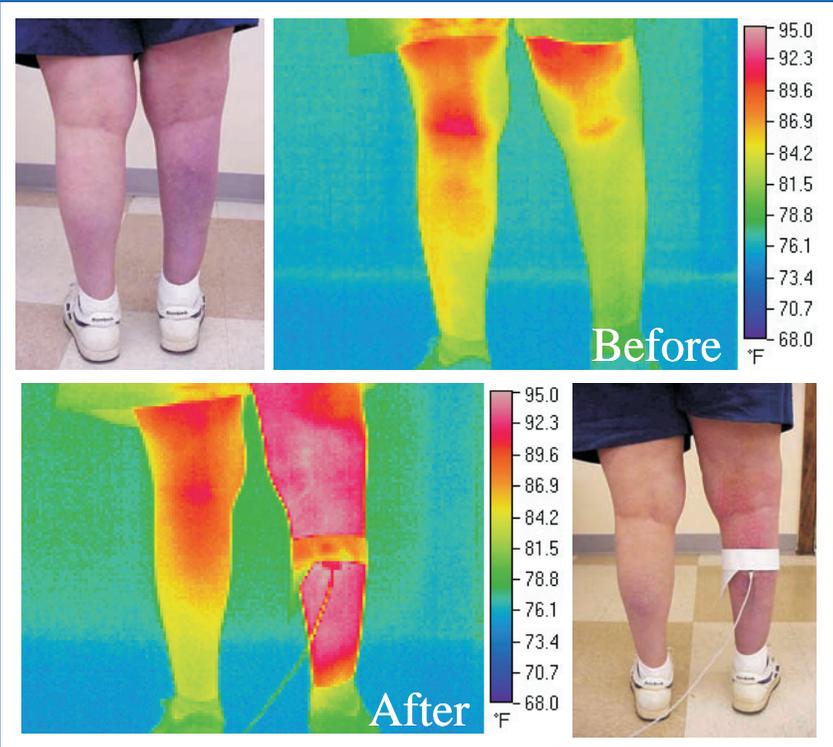
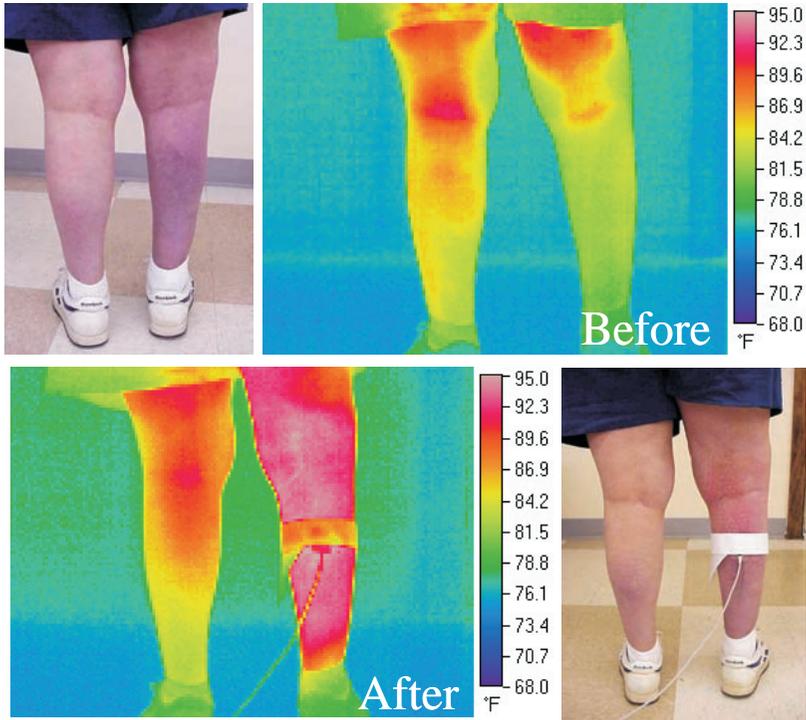


# Physicians' Reference Heat Therapy

Evidence for Use as a Clinical Modality





**On The Cover:** Infrared imaging shows before and after heat therapy treatment of a leg (right) with chronic poor circulation. The leg was wrapped with Adroit Medical's HTP-1500 Continuous Low Level Heat Therapy System. Test protocol monitored skin temperature, pulse rate, oxygen level (SpO<sub>2</sub>) and Perfusion Index (PI) which is relative pulse strength. In this case, the PI increase was 386% at 60 minutes. In addition, skin color is noticeably improved and no signs of skin irritation.



# Physicians' Reference Heat Therapy

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## Evidence for Use as a Clinical Modality

### Introduction

This reference is a collection of studies, articles and regulatory advisories pertaining to heat therapy. Although heat therapy is widely accepted and commonly used for pain relief, there are few resources that address the variety of clinically accepted treatment applications and the use of modern equipment; particularly for the in-home environment. This reference should assist physicians as a quick study of safe vs. unsafe devices, and identify treatment applications with regard to patient need and circumstance. This reference highlights the use of hospital-safe water-circulating heat therapy systems which are cleared by the FDA and approved by Medicare for regular in-home use.

Electric heating pads are themselves the greatest inhibitor of doctor prescribed heat therapy. Sometimes referred to as a “toaster-in-a-blanket” electric heating pads are associated with home fires and personal injury; they are prone to misuse as patients tend to ignore the instructions and warning labels. It is common knowledge that one should never sit or sleep on an electric heating pad, neither should a person with diabetes or patients on oxygen use them, but these things happen all the time.

Fortunately there is an alternative heating system that patients can use continuously, including those who may need to sit or sleep on them; even if they have diabetes or are on oxygen. The solution is water-circulating heating pads, commonly known as “K-pads”, they were originally developed for hospital use. These systems consists of a microprocessor control unit (pump) with a flexible bladder (pad). The system presented in this reference guide is the HTP-1500 manufactured by Adroit Medical Systems, Inc.

Example treatment applications safe for the HTP-1500 system include chronic pain, arthritis, low back pain, fibromyalgia, circulatory disorders, diseases of the musculoskeletal system and connective tissue and a limited scope of cancer pain applications.

## Evidence for Use of Heat Therapy as a Clinical Modality

Heat therapy has been used on patients for essentially all complaints and conditions since recorded time. Heated sand, rocks, water, animal hides, and plant fibers have all been described in ancient medical literature as valid treatments for various ailments. Presumably, trial and error discovered some combinations of heat source and physical complaint worked better than others. Such treatments were described as early as some of the Egyptian papyrus writings. Additional study continued into the Renaissance period but largely fell away with the discovery of electricity and the subsequent fascination with its mysteries.<sup>1</sup>

Palliative use of heat therapy has gradually become a staple of medical care throughout the years with little hard science into its actual effect. Following World War II, some additional research began because of interest in thermal injury seen in large numbers of wounds from modern warfare. Moritz and Henriques (1947) showed that temperature and exposure time determine whether a thermal injury will occur and how extensive an injury will be. Fluid temperatures above 43° C (109.4°F) can produce thermal injuries; thermal injuries will not occur at temperatures below 43° C, although skin lesion development from other factors (e.g., ischemia) may be aggravated.<sup>2</sup>

The Clinical Nursing Skills and Techniques textbook, by Elsevier & Mosby, devotes an entire chapter to the application, use, patient care and treatment when using heat and cold therapy. The following excerpts reflect the degree to which this treatment modality is considered ubiquitous to the care of patients today.

The local application of heat and cold to body parts can have a beneficial effect on patient comfort. In order to know how to use heat and cold therapies safely, the nurse must understand how the body normally responds to temperature variations and the risks connected with these applications. Exposure to heat or cold causes both systemic and local responses. The hypothalamus acts as the thermostat of the body to maintain body temperature at approximately 37° C, or 98.6° F.

Systemically, when the skin is exposed to warm or hot temperatures, vasodilatation and perspiration occur to promote heat loss. As perspiration evaporates from the skin, cooling occurs. In cryotherapy, when the skin is exposed to cool or cold temperatures, the systemic response includes vasoconstriction and piloerection to conserve heat. Shivering occurs in response to cooler temperatures, producing heat through muscular contraction. Local response to heat and cold results

from changes in blood vessel size which affects blood flow to the exposed area. This physiological response explains the effectiveness of warm and cold therapies (Table 40- 1).

When receptors for heat or cold are stimulated, sensory impulses travel via somatic afferent fibers to the hypothalamus and cerebral cortex. The cerebral cortex makes a person aware of temperature sensations. The person can then adapt as necessary to maintain normal body temperature; if cold, the person can put on additional clothing, or if warm, the person can cool down by bathing the face with a tepid damp cloth. The hypothalamus simultaneously controls physiological reflexes needed to regulate normal body temperature. The body also has a protective reflex response for exposure to temperature extremes. Exposure to an extremely hot or cold stimulus sends impulses traveling to the spinal cord, synapsing at the spinal cord, and returning by way of motor nerves to cause withdrawal from the stimulus.

Heating pads are covered and applied directly to the skin's surface, and for this reason extra precautions are needed to prevent burns. The aquathermia pad (water flow pad) consists of a waterproof rubber or plastic pad connected by two hoses to an electrical control unit that has a heating element and motor. Distilled water circulates through hollowed channels in the pad to the control unit where water is heated (or cooled). The nurse can adjust the temperature setting by inserting a plastic key into the control unit. In most health care institutions, the central supply department sets the temperature regulators to the recommended temperature approximately 40.5° to 43° C (105° to 109.4° F). Because of the constant temperature heat control, aquathermia pads tend to be safer than heating pads. If distilled water in the unit runs low, the nurse simply adds more distilled water to the reservoir at the top of the control unit. Rubber and plastic conduct heat, so the pad should be encased in a towel or pillowcase to avoid direct exposure to the skin. The conventional heating pad, used mostly in the home care setting, consists of an electric coil enclosed in a waterproof cover. A cotton or flannel cloth covers the outer pad. The pad connects to an electrical cord that has a temperature regulating unit for high, medium, or low settings. Because it is so easy to readjust temperature settings on heating pads, clients should be instructed not to turn the setting higher once they have adapted to the temperature. It is wise to avoid ever using the highest setting. Due to the risk of injury from heating pads, this treatment is used infrequently in children. The skin of infants and children is thin and fragile and therefore easily damaged. Use special caution in this population. Remain with children during procedure for safety and effectiveness. Assess body temperature gain and loss, which occurs more readily in pediatric clients.

Older adults are more at risk for burns because of loss of heat sensation. Check site frequently during all treatments. Older clients have thin, more fragile skin that is susceptible to burns. Clinical Nursing Skills and Techniques, 6th Edition Chapter 40 (excerpts).<sup>3</sup>

In the physical and rehabilitative medicine fields, heat therapy plays an even greater role in patient treatment and disease management. In the textbook “Wound Care Practice” by Paul J. Sheffield, Ph.D., Adrienne P.S. Smith, M. D. and Caroline E. Fife, M. D. published by Best Publishing Company in 2004, the physiological effects of and recommended utilization of water temperatures from 80 to 104° F (page 609) are divided into four tiers. Each tier is defined by a temperature range and the effects and appropriate wound patient listed for which those temperatures should be used.<sup>4</sup>

In addition to the previously defined uses of heat, the different modalities of heat application are now being studied. Clear indications for use of different types of devices are beginning to be outlined. In an article published in The Spine Journal 2005 Jul-Aug;5 (4):395-403, functional improvement, disability reduction and pain relief were all statistically significantly improved for heat + exercise than for heat, exercise, or self-help instruction booklet. Researchers concluded that combining continuous low-level heat therapy with directional preference-based exercise during the treatment of acute low back pain significantly improved functional outcomes compared with either intervention alone or control. Either intervention alone tended to be more effective than control.<sup>5</sup>

In the National Journal for the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation, an article published in 2003 described a prospective, randomized, parallel, single-blind (investigator), placebo controlled, multicenter clinical trial for overnight use of continuous low-level heat for relief of low back pain. (Arch Phys Med Rehabil Vol 84, March 2003 Overnight Use of Continuous Low-Level Heatwrap Therapy for Relief of Low Back Pain)

Seventy-six patients were included and stratified by baseline pain intensity and gender and then randomized to one of the two arms of the study. Long term (greater than 4 hours) treatment produced significantly better results than placebo (p 0.00005) for mean pain relief, morning muscle stiffness, increased lateral trunk flexibility, and decreased lower back disability by day 4. Adverse events were mild and infrequent. Their conclusion was that overnight use of heat therapy using water circulating pads provided effective pain relief throughout the next day, reduced muscle stiffness and disability, and improved trunk flexibility. Positive effects were sustained more than 48 hours after treatments were completed.<sup>6</sup>

A second study of the same design by the same group, plus three additional centers involved 219 patients. Continuous low-level heat therapy was used for treating acute nonspecific low back pain. Again the results showed significant therapeutic benefits in pain relief, muscle stiffness, and increased flexibility. Disability was also reduced in the heat group. Adverse events were mild and infrequent. This article was published in the Arch Phys Med Rehabil. 2003 Mar;84(3):329-34.<sup>7</sup>

Circulating heat pad therapy attracted enough attention that ECRI did an analysis of fluid circulating heating pads and pumps in 1989. They made the following observations related to fluid circulating heat pads and pumps: analysis of fluid circulating heating pads and pumps in 1989. They made the following observations related to fluid circulating heat pads and pumps:

The use of circulating fluid pumps and pads is recommended for applying longterm mild heating to the skin. Because these devices incorporate good temperature control and safety features, they are especially useful for patients who are sleeping or anesthetized or who have a sensory deficit. In some cases, however, patients may be sensitive to even this mild form of heat therapy. Care should be taken if the treated area is ischemic and with pediatric, diabetic, or geriatric patients.<sup>8</sup>

Hospitals frequently use circulating fluid pumps and pads to apply localized conductive heating directly against the skin to relieve pain and stimulate blood circulation. Electric heating pads are a method of applying conductive heating. Heat from electrically heated wires warms the pad's surface. Electric heating pads can cycle to a surface temperature of 155°F (68°C), which feels hot but is safe for only very short periods. Because their surface temperature can cause a thermal skin injury, these pads are not generally recommended for use unless the patient is supervised or can frequently inspect the condition of the skin.<sup>9</sup>

Newer research is just beginning into the use of continuous low level heat therapy using water circulating heating pads. In what is believed to be the first experiment of its kind, a human leg treated with low level heat therapy from a water circulating pad showed a 28% increase of blood oxygen saturation by infrared oximetry measured in the calf of a healthy adult male who was treated with an application of 100° F and 105° F respectively. Researchers have long known that effective heat therapy (104° F to 113° F) will dilate blood vessels and therefore increase oxygen delivery, but the level of that increase has never been measured.<sup>10</sup>

Previous studies concluded that heat directly applied increased blood flow in

the skin of diabetics by 21%. They also concluded that "hot packs" should not be used because of temperature control issues and the potential risk of a burn injury. A recent FDA consumer advisory recommended the use of heat circulating therapy systems to avoid the risk of injury associated with electric heating pads.<sup>11,12</sup>

A second study showed the benefits of localized heat therapy to safely and effectively increase blood flow in the limbs of individuals diagnosed with diabetes. The perfusion index (PI) is a relative measurement of pulse strength and an indication of the amount of blood delivered to the skin and tissue. Following the application of heat by water circulating pad, an initial PI value of 0.15 climbed 500% to 0.75 after 30 minutes of therapy. This test indicates that water circulating heat therapy treatment may have a role to play in both wound care treatment and limb salvage.<sup>13</sup>

Circulating Fluid Heat Therapy provides continuous heat at a temperature low enough not to cause burns. This therapy is safe as long as the patient is checked periodically, the device is operating properly, and the patient is not overly sensitive to heat. Patients may increase the temperature of heating pads based on perceptions of temperature that may not be accurate or safe. But they cannot increase the temperature of water circulating heat pads to an unsafe level. Because of the broad safety parameters of these devices, they have roles beyond those of the typical heating pad and may have exciting new roles to play in the management of chronic wounds and severely vascular compromised limbs in the future.

Additional articles concerning the effectiveness of continuous low-level heat therapy are included with the reference material mentioned above. Also included are articles concerning dangers of electric heating pads when used in the home by the elderly or in the presence of other medical devices.

- 
- 1 Modern Heat Therapy. Reis M. Business Briefing: US Pharmacy Review 2004.
  - 2 The Relative Importance of Time and Surface Temperature in the Causation of Cutaneous Burns A. R. Moritz, M.D. and F.C. Henriques, Jr., Ph.D. 1946.
  - 3 Clinical Nursing Skills and Techniques, 6th Edition, Chapter 40, Potter, Patricia A., RN, MSN, PhD (Cand) (Barnes-Jewish Hospital); Perry, Anne Griffin, RN, MSN, EdD (St Louis Univ Health Sciences Center) 2003.
  - 4 Wound Care Practice; Paul J. Sheffield, PhD, Senior Editor, Caroline E. Fife, MD, Adrienne P. S. Smith, MD, Co-Editors, Published by Best Publishing Company Flagstaff, AZ 2004.
  - 5 Treating acute low back pain with continuous low-level heat wrap therapy and/or exercise: a random controlled trial. The Spine Journal 5. 2005.
  - 6 Over Night Use of Continuous Low-Level Heatwrap Therapy for Relief of Low Back Pain. Arch Phys Med Rehabilitation Vol 84. March 2003.

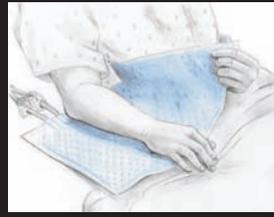
- 7 Continuous low-level heatwrap therapy for treating acute nonspecific low back pain. Arch Phys Med Rehabil. Mar; 84: 329-34. 2003.
- 8 Circulating Fluid Heat Therapy Devices. ECRI. Vol. 18, No. 5. May 1989.
- 9 Powered Heat Therapy. Water vs. Electric. Adroit Medical Systems. 2006.
- 10 The Effect of Localized Heat Therapy on Regional Oxygen Saturation. Adroit Medical Systems. 2006
- 11 Does Local Heating Really Help Diabetic Patients Increase Circulation. Jerold Scott Pterofsky, Ph.D., et alt.
- 12 FDA/ CPSC Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads. 1995.
- 13 HTP-1500 Heat Therapy System Increases Blood Perfusion In Diabetic Limb Case Study 81606. Adroit Medical Systems. 2006.

### **Additional Heat Therapy References**

- A. Continuous Heat Therapy: Can It Have An Impact. Andrienne Berarducci, Ph.D., ARNP, BC. Arthritis Practitioner. Vol. 2 Issue 1. January 2006.
- B. Continuous Low-Level Heat Wrap Therapy for the Prevention and Early Phase Treatment of Delayed-Onset Muscle Soreness of the Low Back: A Randomized Controlled Trial. John M. Mayer, DC, Ph.D. et alt. Arch Phys Med Rehabil Vol 87, October 2006.
- C. United States Patent Application Publication. Pub. No.: US 2008/0177358 A1. July 2008.
- D. What Is Back Pain? US Department of Health and Human Services. September 2006.
- E. Heat Therapy Provides Effective for Acute Lower Back Pain. Jeff Minered. Medpage Today. January 2006.
- F. Hands-On Help, Hot and cold packs. Terri J. Metules, RN, BSN. www.rnweb.com Vol 70, No.1 January 2007.
- G. Impact of Continuous Low Level Heatwrap Therapy in Acute Low Back Pain Patients: Subjective and Objective Measurements. Birgit Kettermann, Ph.D., et al. Clinical Journal of Pain. Vol 23, No. 8 October 2007.
- H. The Effect Of Topical Heat Treatment On Trapezius Muscle Blood Flow Using Power Doppler Ultrasound. Erasala GN, et alt. Physcial Therapy. Vol 81 No 5 May 2001.
- I. Local Heating Versus Distant Heating. Justus F. Lehmann, Ed., 3rd ed., Baltimore: Williams & Wilkins, pp. 424-425, 1982.
- J. Biophysical Effects Of Temperature Elevation. Susan L. Michlovitz, F.A. Davis Company: Philadelphia, p 100, 1986.
- K. Topical Heat Provides Pain Relief of Delayed Onset of Muscle Soreness of the Distal Quadriceps Muscle. Weigand, K., Hengehold, D., Knight, E., Combs, L., McNutt, B., Harris, H., Stevenson, S., Dusley, G., FACSM. Medicine & Science in Sports & Exercise. PS75 May 1999.
- L. Using heat therapy for pain management. Chandler A et al., Art & Science Clinical Practice. August 2002.
- M. UT Heat Therapy Proposal, Adroit Medical Systems. 2006.
- N. Low Level Heat Therapy on Perfusion. Adroit Medical Systems. 2007



# HEAT THERAPY



## Example ICD-9 Codes

- ✓ **Primary ICD-9 Should Be For Chronic Pain.**
- ✓ **A secondary ICD-9 code may be chronic circulation or other chronic pain condition.**

### Example Primary ICD-9 Diseases of the Musculoskeletal System and Connective Tissue

- 714.0** Rheumatoid arthritis
- 714.4** Chronic postrheumatic arthropathy
- 715.0** Osteoarthritis, generalized
- 717.9** Unspecified internal derangement of knee
- 719.4** Pain in joint
- 719.9** Unspecified disorder of joint
- 724.2** Lumbago
- 724.5** Backache, unspecified
- 724.6** Disorders of sacrum
- 724.7** Disorders of coccyx
- 724.8** Other symptoms referable to back
- 724.9** Other unspecified back disorders
- 726.5** Enthesopathy of hip region
- 728.9** Unspecified disorder of muscle, ligament, & fascia
- 729.0** Rheumatism, unspecified & fibrositis
- 729.5** Pain in limb

### Chronic Pain

- 338.28** Other chronic postoperative pain
- 338.29** Other chronic pain
- 729.5** Pain in limb
- 724.5** Backache, unspecified
- 780.96** Generalized pain

### Example Secondary ICD-9 Peripheral Circulatory Disorders

- 249.7** Secondary diabetes mellitus with peripheral circulatory disorders [0-1]
- 250.7** Diabetes with peripheral circulatory disorders [0-3]
- 443.9** Peripheral vascular disease, unspecified
- 443.81** Peripheral angiopathy in diseases classified elsewhere

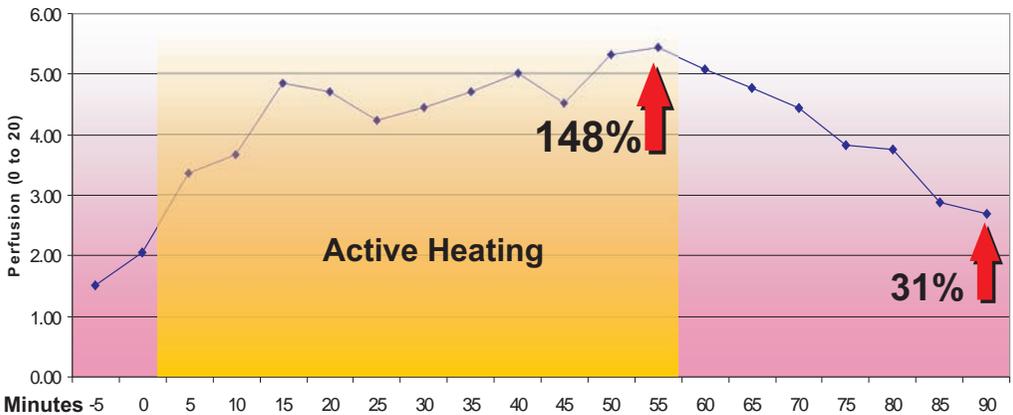
**Not A Complete List**

# Adroit's HTP-1500 Safely Increases Perfusion 150%\*

Perfusion is a relative measure of pulse strength. Continuous low level heat therapy increases perfusion by safely dilating blood vessels and relaxing muscle tissue; thus allowing for increased blood flow and improved oxygen delivery. In addition, effective heat therapy (beginning at 104°F)<sup>1</sup> stimulates thermoreceptors in tissue signaling comfort to the brain and reducing pain transmissions.<sup>2,3</sup> Therefore, increased blood flow, improved oxygen delivery and pain relief, are the clinical results of continuous low level heat therapy.

In the example below, Adroit's HTP-1500 system dramatically increases perfusion 150% on average in the feet of elderly volunteers, with a 31% residual increase 30 minutes after therapy.

## Low Level Heat Therapy Effect on Perfusion, 60 Minute Tests



\*Averages are consistent in healthy vs. unhealthy feet. Results vary depending on test protocol and evaluation methods.

1. Therapeutic Heat and Cold. Justus F. Lehmann, ed. 3rd ed., Baltimore: Williams & Wilkins, pp. 425-425, 1982.

2. Using Heat Therapy for Pain Management. A. Chandler, et al, Nursing Standard, 17(9) pp. 40-42, 2002.

3. Thermal Agents in Rehabilitation. Susan L. Michlovitz, F.A. Davis Company: Philadelphia, p. 100, 1986.

# The Effect of Localized Heat Therapy on Regional Oxygen Saturation

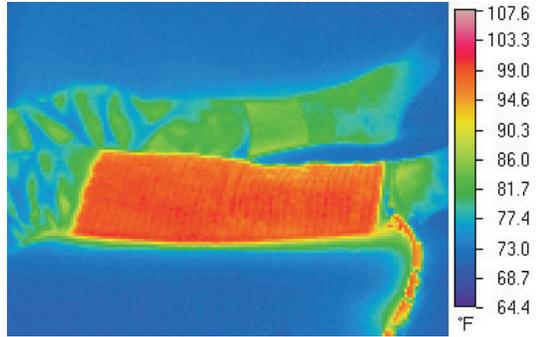
In what is believed to be the first experiment of its kind, infrared oximetry was used to record increased regional blood oxygen saturation (rSO<sub>2</sub>) in a human leg treated with “localized heat therapy.” A stunning 28% increase of blood oxygen saturation was measured in the calf of a healthy adult male who was treated with an application of 100°F and 105°F respectively. Researchers have long known that effective heat therapy (104°F to 113°F) will dilate blood vessels and therefore increase oxygen delivery. But the level of that increase has never been measured.

The test utilized a model HTP-1500 heat therapy system from Adroit Medical Systems, Inc., and a INVOS infrared oximetry unit from Somanetics Corporation. Encouraged by the preliminary findings, the companies intend to pursue clinical research with an emphasis on treatment for diabetic patients. Pending results of that study research may be expanded to wound care treatment.

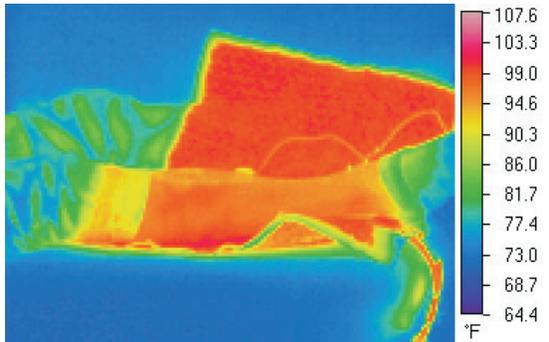
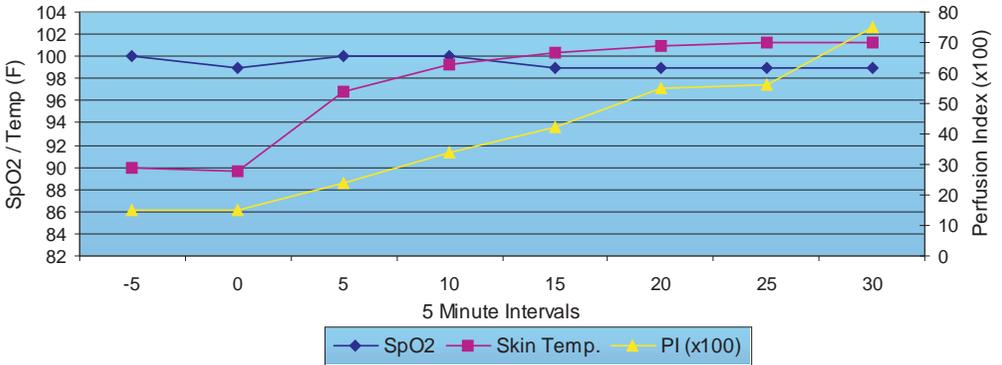


**Test Method**

A HTP-1500 heat therapy pump with pad was heated to 107°F. A transfectance sensor was taped to the diabetic's inside right calf. A skin temperature probe was also adhered to the calf. Base line readings were recorded 5 minutes prior to the application of heat. The pad was wrapped around the lower right leg. Blood oxygenation (SpO2) and perfusion (PI) data were recorded with a Masimo RAD5 Pulse Oximeter. Test duration was 35 minutes. Infrared images were taken with a Micron thermal camera.

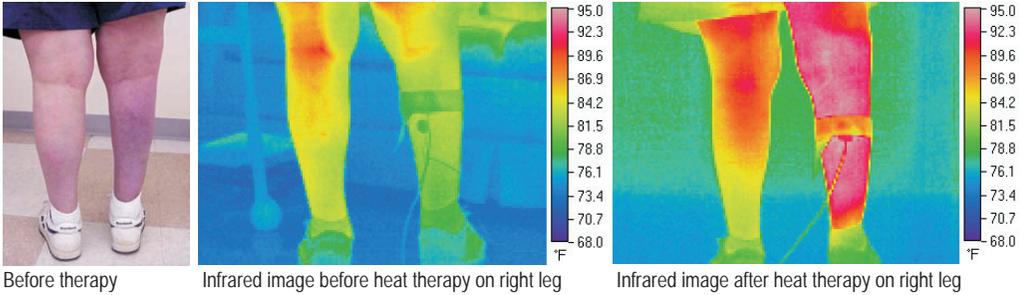


**Data** Temperature, SpO2 and Perfusion Index (x100)



**Conclusion**

Subject's oxygen saturation (SpO2) reading prior to therapy was 100 and did not increase during the test. However, the perfusion index (PI) was low prior to therapy but showed a substantial increase following application of heat. Initial PI value was .15 and climbed 500% to .75 in 30 minutes. PI is a relative measurement of pulse strength and an indication of the amount of blood delivered to skin and tissue. Test indicates the HTP-1500 heat treatment increased the amount of arterial blood flow to the diabetic limb.



**Introduction**

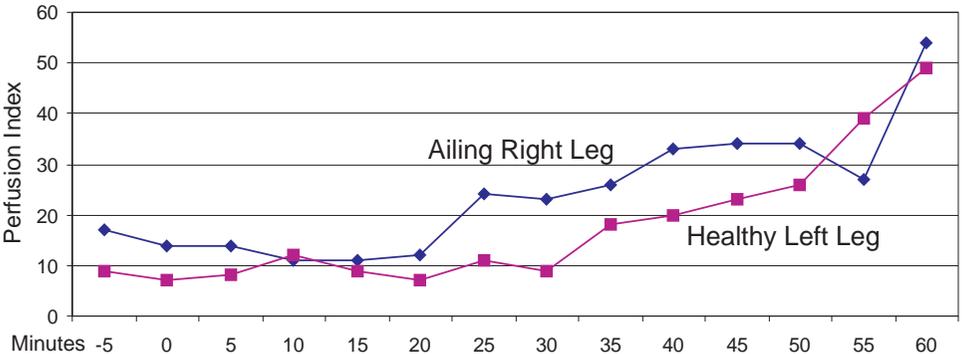
The purpose of this test is to compare and measure the effects of heat therapy on the lower legs of a person with one ailing and discolored leg.

Research has shown that effective localized heat therapy begins at a temperature of 104°F (40°C).<sup>1,2</sup> This temperature is an accepted threshold for muscle relaxation and improved blood flow. It is also a widely accepted fact that water is a very efficient way to warm tissue because of its high specific heat and thermal conductivity.<sup>3</sup> Indeed, hydrotherapy (warm water immersion) is a recommended treatment for diabetics to increase circulation.<sup>4</sup> Yet despite the seemingly simplistic nature of heat therapy, controlled treatment options generally impractical and require a doctor's office visit.<sup>5</sup> An alternative for at-home treatments can be found in the HTP-1500 water-circulating heat therapy system. Originally sold to hospitals, this pump with pad combination is available by prescription for home use. The HTP-1500 can simulate immersion therapy by enveloping the limb with temperature specific water therapy. The FDA issued a public health advisory recommending systems like this as a safe alternative to electric heating pads.<sup>6</sup>

**Test Method**

A HTP-1500 heat therapy pump with pad was heated to 107°F. A transfectance sensor was taped to the back side of volunteer's right calf. This leg has noticeable skin discoloration. A skin temperature probe was also adhered to the calf. The heat therapy pad was wrapped around the volunteer's lower right leg. Blood oxygenation (SpO2), pulse and perfusion (PI) data were recorded at 5 minute intervals with a Masimo RAD5 Pulse Oximeter. The volunteer received 60 minutes of heat therapy. Photos and infrared images of both legs were taken before and after therapy. This same test was repeated on the healthy left leg.

**Data** Combined Perfusion Index (x100)

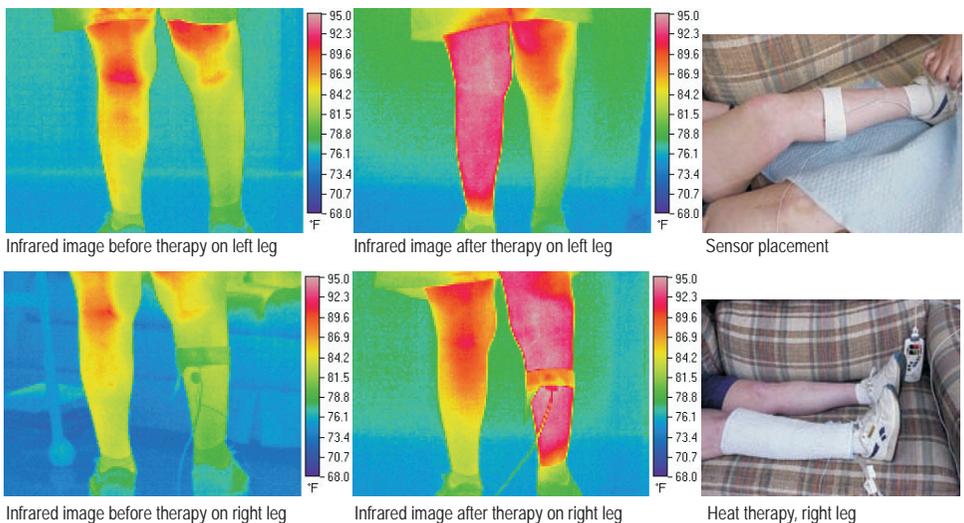


## Conclusion

The application of heat therapy produced similar results on both legs with few exceptions. The perfusion index for each leg increased virtually the same amount despite the fact each leg had a different beginning and ending value. Higher PI values in the right leg are believed caused by the visible subcutaneous collection of blood which the sensor was placed over. As such, the prevailing condition skewed right leg PI values making them appear stronger than left leg PI values. The right leg is clearly not as healthy as the left leg. Therefore, the PI values in the right leg should only be interpreted as relative and not an absolute indicator of health. Still, improvement in PI values was consistent for both legs. Interestingly the oxygenation saturation (SpO<sub>2</sub>) was also higher in the right leg and did not increase with the application of heat therapy. SpO<sub>2</sub> in the left leg did rise steadily in the leg once heat therapy began. A noticeable improvement in the ailing right leg's color was evident in before and after photographs.

Infrared images show strikingly different skin surface temperatures of the legs. Before applying heat therapy the right leg's skin temperature was approximately 81°F, which is 10°F less than average skin temperature for a healthy person.<sup>7</sup>

These tests demonstrate that the HTP-1500 heat therapy system amply increased the amount of arterial blood flow to both legs. Additional tests are warranted to evaluate the duration and residual benefits of continuous low level heat therapy.



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2. Physical Medicine and Rehabilitation, Kottke FJ, Lehmann JF, Fourth Ed. 1990.
3. The Influence of Warm Hydrotherapy on the Cardiovascular System and Muscle Relaxation. Petrosky J. The Journal of Neurological and Orthopaedic Medicine and Surgery 21(3) 2003.
4. Hot-Tub Therapy for Type 2 Diabetes Mellitus. Hooper PL, N Engl J Med 341:924-925 1999.
5. A New Look at Heat Treatment for Pain Disorders, Part 2 O'Conner A, McCarberg B, American Pain Society 15(1) 2005.
6. FDA Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads. 1995
7. Temperature of a Healthy Human (Skin Temperature). The Physics Factbook. Sept. 2006.

# Warning

## Electric Heating Pad Burns and Recalls

Electric heating pads are dangerous and should not be used to treat **chronic pain**. The FDA and several medical publications strongly discourage the use of electric heating pads with patients who are elderly, have diabetes, or are on oxygen.



FDA Warns Home Health Agencies To Not Use Electric Heating Pads  
Advises Instead To Use Hospital Approved Heat Therapy Systems

FDA/CPSC Public Health Advisory Dec 1995: Hazards associated with the use of electric heating pads

FDA Announces Electric Heating Pads Are Enforcement Priority  
Warns US Market Flooded With Unsafe Electric Heating Pads

FDA News, November 2007: CDRH Highlights Fiscal 2008 Enforcement Priorities

FDA Recalls 300,000 Class 1 Electric Heating Pads

Loose Connection May Cause Short Circuit. Risk of Burn Injuries or Fire.

FDA Recalls: <http://www.fda.gov/cdrh/recalls/recall-020907.html>

### The Hospital Safe Alternative

#### Chronic pain patients qualify

- ★ Requires regular treatment exceeding 30 minutes
- ★ Requires sitting or sleeping (i.e. low back pain, hip, shoulder)
- ★ Has diabetes or is insensate
- ★ On oxygen
- ★ Incontinent

### Adroit HTP-1500 Heat Therapy Pump FDA 510k & Medicare Approved E0217



# Medical Literature: Electric Heating Pad Burns

## Analysis of Burns Caused by Long-Term Exposure to a Heating Pad

- A heating pad at the low power setting can produce a burn.

J Burn Care Rehabil 1991; 12:214-7

## Cutaneous Reactions of the Extremities of Diabetics to Thermal Trauma

- Burns often cause severe skin lesions on the lower extremities of diabetics.

Acta Med Scand 1954; V198:319-25

## Preventing Burns in Older Patients

- Electric heating pads are a common cause of burns in older adults with cognitive deficits.

American Family Physician 2006; V74:10

## Electric Heating Pad Burns

- The physician must not underestimate the severity of burn injury caused by electric heating pads.

J Emergency Med 1994; V12(N)6:819-824

## Burn Injuries

- Electrical burns are particularly worrisome because of deeper injuries not evident on initial inspection.

Medical Aspects of Disabilities, Springer Publishing 2005

## Foot Care for People with Diabetes

- Don't use an [electric] heating pad on your feet.

American Family Physician 1999; V60:3

## Fires in the Home Care Setting

- Patients injured or killed were receiving supplemental oxygen and in each case, over the age of 65.

The Joint Commission, Sentinel Event Alert 2001; Issue 17

## Using Oxygen At Home

- Avoid using [electric] heating pads while wearing oxygen. The control box may cause a spark.

Healthtouch Online, www.healthtouch.com, accessed July 2007

### Analysis of Burns Caused by Long-Term Exposure to a Heating Pad

Kenneth B. Dills, MD  
Johns, Tex

The potential for causing a second-degree burn by extended exposure to an electric heating pad was evaluated in a single model. Extrapolation of reported results from experiments in shrewed rats and a hypothesis indicated that a heating pad at the low power setting can produce a burn within a threshold time of approximately 12 to 20 hours. [7 cases]

Case Reports 1993;13:111-7

Electric heating pads are used routinely for a multitude of applications in home, institutional, and clinical settings. The heating pad is a very common device that is familiar to a large cross-section of the population and is normally considered to be generally benign in function. However, because of the inherent possibility of producing a surface or an element term...

and injury as a function of temperature indicate that the second-degree injury would have developed within a time frame of between 12 and 20 hours.

**METHODS**  
Temperature Measurements

### The Joint Commission

#### Sentinel Event Alert

Issue 17 / March 3, 2001

**Lessons Learned: Fires in the Home Care Setting**

In the 13 cases studied, the home care organizations have identified central root causes that are brought to the attention of these sentinel events involving fires in the home. These root causes encompass patient care practices, the company, the environment of care, and communication factors. With respect to patient care practices, the most common of these root causes are: (1) inadequate assessment/identification of high-risk patients, (2) improper equipment use, (3) inadequate monitoring of oxygen use, (4) inadequate training, and (5) flammable clothing. These home care sentinel events resulted in the death of a patient and the loss of function or permanent impairment for four other patients. Oxygen therapy was administered to a contributing factor in each of these cases.

**Root Causes Identified**

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### Burn Injuries

EDWIN F. RICHTER III, MD

OVER 3 MILLION burn injuries occur in the United States per year. Fire is the most common cause of burn injuries, but contact with extreme heat (radiant, electric, chemical, or thermal) is also a common cause of burn injuries. Each year, about 10 million Americans have burn injuries, and about 100,000 have deep, serious burns that require hospitalization. Each year, about 10 million Americans have burn injuries, and about 100,000 have deep, serious burns that require hospitalization.

### Selected Topics: Wound Care

**ELECTRIC HEATING PAD BURNS**

Trinity B. Hill, MD, FRCPC, FRCPC, FRCPC, FRCPC, FRCPC

Healthtouch Online: At Home Health

**USING OXYGEN AT HOME**

**GENERAL INFORMATION:**

What is supplemental oxygen?

- Oxygen is an invisible gas that your body needs to live. Your lungs take it out of the air you breathe and put it into your blood. Your blood takes it to all the cells and organs of your body. Your cells use oxygen and put the waste out to be used by the lungs.
- You may need supplemental oxygen if you have problems with your heart or blood. Your body may also need extra oxygen after some surgery. You may need extra oxygen when breathing is high altitude or when you are recovering from a serious illness.
- Supplemental oxygen is thought of as a drug. You must use it properly and in the right amount. If you use too much, you can get sick. Getting sick can be dangerous.

### American Family Physician

A peer-reviewed journal of the American Academy of Family Physicians

1999; V60:3

#### Editors

#### Preventing Burns in Older Patients

AMY B. HARRIS, MD  
Albert Einstein College of Medicine  
Bronx, New York

For older adults, burns and lacerations injuries are the second leading cause of death from accidental injury in the home. "Oxygen therapy and alcohol use contribute to many of these injuries. However, the use of dementia is a risk factor for burns and falls is not cited. Primary care physicians are increasingly aware of these risks and often are encouraged by primary care physicians.

Accidents while walking on a home care setting are a leading cause of injury in older adults. However, primary care physicians often fail to discuss the availability to guide physicians in a checklist history of safety hazards. It should ask patients and caregivers about cognitive impairment. If you have patients from walking with significant cognitive deficits.

Find top water burns occur despite and inadequate supervision of pad use. The recommended practice is to research how to use the pad in the bathroom of older persons review the need for adaptive wear.

### American Family Physician

Sept 1, 1999; V62:39A

#### Foot Care for People with Diabetes.

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How does diabetes affect my body?

Diabetes makes your blood sugar level higher than normal. A high blood sugar level can damage your blood vessels and nerves. Damage to the blood vessels in your feet may cause your feet to get less blood. Damage to the nerves may cause you to lose some of the feeling (sensations) in your feet.

Why should I worry about my feet?

People with diabetes often have foot problems. Part of the problem is that if you have any loss of feeling in your feet, it's hard to tell if you have a blister or sore. Sores may take a long time to heal. If foot sores aren't taken care of, you might get a foot ulcer (a very serious, deep sore). If the ulcer then gets infected, you may need to go to the hospital for treatment or even have part of your foot amputated (removed). The good news is that with proper care you can prevent foot problems.

How should I care for my feet to avoid serious problems?

Careful control of your blood sugar is the key to avoiding foot problems. It may help to monitor (check) your blood sugar level every day at home (this is called blood glucose self-monitoring). Be sure to follow your doctor's advice on diet, exercise and medicine. Here are some other things you can do to take care of your feet if you have diabetes:

- If your toenails are too thick or if they crack when you try to cut them.
- If your feet sweat easily, keep them dry by dusting them with a non-medicated powder on shoes and stockings.
- Loosen your laces at the foot of the bed so you don't pressure your toes or heels, or on the bony spots of your feet.
- Have your doctor look at your feet at every office visit (at least one time every year) or whenever you notice anything that seems wrong.
- What things should I avoid to care for my feet?
- Don't use any instruments on your feet (except nail clippers) without your doctor's advice.
- Don't use calluses or corns, or use medicine to remove them, unless your doctor tells you it's okay.
- Don't soak your feet.
- Don't use hot water, a heating pad, or a massage on your feet.
- Don't go barefoot.
- Don't use adhesive tape or chemicals on the skin of your feet.

### Acta Med Scand. Vol. 198, pp. 319-325, 1975

#### Cutaneous Reactions of the Extremities of Diabetics to Local Thermal Trauma

Felix Litzner  
From the Department of Medicine, University of Umeå, Umeå, Sweden

**ABSTRACT.** An earlier report described cutaneous lesions, consisting of erythema with or without necrosis, on the legs and/or feet of diabetic patients and the cause was suggested to be an altered reaction to environmental factors such as outdoor temperature. The present investigation concerns the cutaneous reactions to transcutaneous heat treatment with the use of leg and forearm of 26 diabetics and 26 controls. Penetration within the area of transcutaneous heat treatment with either hot or cold was observed more often in diabetics than in controls. They occurred more frequently on the leg than on the forearm. As the diabetics were 26, penitence were observed only when the duration of diabetes was 10 years or more but seldom in young patients with diabetes of shorter duration. The reactions of diabetics were not significantly related to the concentration of glucose in diabetes over 20. In the controls, cutaneous reactions were observed after the concentration with heat of a lower temperature than that which caused penitence to appear in corresponding patients. The initial skin lesions in diabetics differed from those in controls in that they were more extensive and more persistent. The initial skin lesions in diabetics developed an intensely red border around the area of experimental heat or cold treatment. These patients were either elderly diabetics or younger patients with diabetes.

It was suggested that these lesions were due to an altered reaction to diabetes to various precipitating factors, chiefly outdoor temperature. It was therefore considered of interest to investigate whether or not the skin of diabetics compared to that of controls has an altered reaction to experimentally induced trauma. To the author's knowledge, there are no systematic, experimental studies of the possible differences between diabetics and non-diabetics with respect to cutaneous reactions to environmental conditions. Heat and cold were used in producing the reactions in small areas on the skin of legs and forearms.

The effects of experimental local thermal trauma on the skin of humans and animals have been studied by Leach et al. (14), Levin and Lutz (15) and others. The lesions they described are generally those seen clinically as a result of burns, i.e. erythema, blisters and destruction of the skin (15, 21). Local application of heat or cold may also cause capillary stasis, with increased permeability of small blood vessels (16, 20). The clinical observation that diabetic patients with angiopathetic changes were tolerant to radiation than non-diabetic stimulated Cohn et al. (17) to undertake an experimental investigation which de-

# Electric Heating Pad Burns



# Electric Pads Can Cook Bologna



or Skin



**Fact: Ground Beef cooks at 160°F  
Electric Pads can get hotter than that!**

# FDA Advisory Against Electric Heating Pads

## FDA/CPSC Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads

(We encourage you to copy and distribute this Advisory.)

December 12, 1995

To: Safety Directors	Risk Managers
Biomedical/Clinical Engineers	Nursing Homes
Directors of Nursing	Hospices
Hospital Administrators	Home Healthcare Agencies

The Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) have received many reports of injury and death from burns, electric shocks, and fires associated with the use of electric heating pads. These incidents have occurred in nursing homes, hospitals, and at home. In most cases, they could have been avoided by careful inspection and proper use of the heating pad.

Every year, the CPSC receives an average of eight death reports associated with the use of heating pads.<sup>1</sup> Most deaths are caused by heating pad fires and involve persons over the age of 65. Heating pad fires can occur when broken or worn insulation of the electric wires in the heating pad causes the pad to ignite or when electrical cords are cracked or frayed.

CPSC estimates that more than 1,600 heating pad burns are treated each year in hospital emergency rooms.<sup>2</sup> Most injuries are direct thermal burns not caused by fire. About 45 percent of those injured are over the age of 65.

An electric heating pad is usually regarded as a relatively "safe" household product commonly used to treat sore muscles or joints; however, it can cause harm if not used properly. A heating pad can be dangerous for patients with decreased temperature sensation, diabetes, spinal cord injuries, patients who have suffered a stroke, patients taking medication for pain or sleeplessness or those who have been drinking alcohol. Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting.<sup>3</sup>

FDA recognizes that most hospitals today use a circulating hot water pad or a hypo/hyperthermia machine on patients who require such heat therapy. The temperature of these devices is thermostatically controlled, allowing them to be used more safely on a sleeping or unconscious patient when properly supervised by a health professional.

Individuals at particular risk for electric heating pad injuries are:

Infants, since the heating pad would cover a large area of their small bodies. In addition, they may be unable to move when burned.

Persons who may be unable to feel pain to the skin because of advanced age, diabetes, spinal cord injury, or medication.

FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads:

**ALWAYS --**

- 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.
- Keep removable cover on pad during use.
- 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.)
- Unplug heating pad when not in use.
- Read and follow all manufacturer's instructions on heating pad or on outside package prior to use.

**NEVER --**

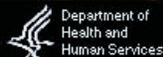
- Use on an infant.
- Use on a person who is paralyzed or has skin that is not sensitive to temperature changes.
- Use on a sleeping or unconscious person.
- Use in an oxygen enriched environment or near equipment that stores or emits oxygen.
- Sit on or against a heating pad.
- Crush or fold a heating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

If you have any questions with regard to this Advisory, please contact Joan M. Rudick, Office of Surveillance and Biometrics, CDRH, FDA, HFZ-510, 1350 Piccard Drive, Rockville, MD 20850, or FAX at 301-594-2968.

In-home devices that were formerly for use by healthcare professionals only, must have FDA 510k Clearance. Therefore heat therapy pumps that do not have a FDA 510k cannot legally be prescribed for in-home use.



U.S. Food and Drug Administration



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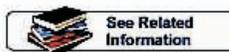
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TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart A--General Provisions

Sec. 890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental

Additionally, a Class II device (i.e. heat pump) must have FDA 510k Clearance if prescribed to diabetic patients.

scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2321, Jan. 14, 2000]

Database Updated April 1, 2007

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Center for Devices and Radiological Health / CDRH

# Benefits and Reasons for Continuous Low Level Heat Therapy

## HTP-1500 Microprocessor Controlled Heat Therapy System

### Arthritis

**FDA approved for use continuous with an unconscious patient.**

*Unlike electric heating pads, the HTP-1500 can be sat on, slept on, and used continuously without fear of electric shock, burn or fire. The FDA advises against the use of electric heating pads and recommends water-circulating heat therapy systems like the HTP-1500 instead.<sup>1,2</sup>*

### O2

**UL approved for use in the presence of oxygen and medical equipment.**

*Unlike electric heating pads<sup>3,4</sup> the HTP-1500 is approved for use in an Operating Room. This means it can be used in the presence of gases such as oxygen. Also, the HTP-1500 is electrically shielded and will not interfere with other medical equipment that may be present.*

### Diabetes

**FDA approved for use with diabetic patients.**

*Unlike electric heating pads, the HTP-1500 can be used safely with diabetic patients. Diabetic patients should never use an electric heating pad because there is a risk of shock, burns or fire.<sup>5,6</sup> Diabetic patients may use the HTP-1500 because it uses temperature controlled water through a flexible pad that cannot shock, burn or cause a fire. The HTP-1500 has been sold to hospitals since 1998 and has never been associated with a skin injury. Controlled water temperature therapy is safe and effective for diabetics.<sup>7,8</sup>*

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1 FDA Public Health Advisory, Hazards associated with the use of electric heating pads, Dec 1995

2 Analysis of Burns Caused by Long-Term Exposure to a Heating Pad, Care Rehabil, 1991

3 Electric Heating Pad User Manual, Battle Creek Equipment, 2002

4 Liquid Oxygen System User Manual, Precision Medical, 2006

5 The Electric Blanket and Heating Pad Litigation Group, American Association for Justice, Jan 2007

6 Foot Care for People with Diabetes, American Family Physician, Sept 1999

7 Hot Tub Therapy Helps Diabetics, New England Journal of Medicine, Reuters Health, Sept 1999

8 Does Local Heating Really Help Diabetic Patients Increase Circulation, Journal of Neurological and Orthopaedic Medicine and Surgery

# Additional Heat Therapy Benefits

## Fibromyalgia

*“The 3 most commonly used interventions were nonmedicinal; rest, heat, and distraction.”<sup>1</sup>*

*“...heat pads also aid in a fibro massage. These are applied after the massage and help settle the muscles down while relaxing the nerve endings.”<sup>2</sup>*

## Pain Disorders

*“This research also shows that only low levels of continuous topical heat (approximately 40°C or 104°F) are needed to increase deep tissue temperature and blood flow. Heat transfer is directly related to the temperature gradient, the surface area covered, and the duration of application. Low-level heat from nonelectric heating pads appears to provide better safety than electric heating pads.”<sup>3</sup>*

## Limited Cancer Applications

*“DESCRIPTION: Local hyperthermia involves the use of heat to make tumors more susceptible to cancer therapy measures.*

*POLICY: (A) Local hyperthermia is covered when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies.”<sup>4,5</sup>*

*“Pain-relieving medications. To relieve pain during a sickle crisis, your doctor may advise over-the-counter pain relievers and application of warm heat to the affected area.”<sup>6</sup>*

*“Non drug treatments: ...Physical therapists can use gentle exercises and heat and cold treatments to help with sickle cell disease pain.”<sup>7</sup>*

- 
1. An internet survey of 2,596 people with fibromyalgia, BMC Musculoskeletal Disorders 2007.
  2. Fibromyalgia and Massage Therapy, Fibro & Fatigue Today Winter 2008
  3. A new look at heat treatment for pain disorders, American Pain Society Vol.14, No.6 2004
  4. Hyperthermia For Treatment of Cancer, CHAMPVA Policy Manual Chapter 4, Sec. 4.6 2002
  5. Medicare Coverage Issues Manual, Transmittal 131, HFCA-Pub. 6, 35-49, Nov 2000
  6. Sickle cell anemia, Treatment, MayoClinic.com, Tools for Healthier Lives, Mar 2007
  7. StopPain.org Dept Pain Medicine & Palliative Care, Beth Israel University Hospital, No date

Find more heat therapy references at [adroitmedical.com](http://adroitmedical.com)

# Notes



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Dr. Edwards is a surgeon and former Medicare Medical Director at SADMERC Palmetto GBA (Statistical Analysis Durable Medical Equipment Regional Carrier). Dr. Edwards is an expert in Medicare policy for durable medical equipment including wheelchairs, power and manual mobility devices, cushions, orthotics, braces, and prosthetics, artificial limbs, drugs, IV products, diabetic supplies, diabetic shoes and inserts, and enteral and parenteral nutrition, wound and ostomy care products and treatments, heat therapy, cold therapy and electric heating pads. He is also an expert in HCPCS Level II Coding.

Dr. Edwards is the author of Evidence for Use of Heat Therapy as a Clinical Modality.

Physicians' Reference Heat Therapy  
compiled and edited by  
Adroit Medical Systems, Inc.

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## HTP-1500 Heat Therapy System

Safe and Effective for Hospital Use  
and In-Home Treatments

