

# Anodyne<sup>®</sup> Therapy System Professional System 480 Policy and Procedure Manual

## 1.0 Title of Modality: Monochromatic Infrared Photo Energy (MIRE™)

- 1.1 **Definition:** A single wavelength of infrared light (890 nm) is emitted from 60 light-emitting diodes per therapy pad. This energy penetrates the skin and temporarily increases circulation and reduces pain.

## 2.0 Infrared Therapy Applications

- 2.1 - Increase local circulation  
2.2 - Decrease pain

## 3.0 Billing Information

- 3.1 97026 – Infrared, one or more areas (Physical Medicine Modality). Bill one unit per treatment unless your payor/intermediary recommends a different code. Check local policies for coverage, indications of use and appropriate diagnosis codes for skilled use of infrared.
- 3.2 Medicare Billing Only - Always add modifier (GP for Physical Therapy; GO for Occupational Therapy)

## 4.0 Infection Control

- 4.1 When Anodyne is used with multiple patients, always place a *clear* plastic barrier over the area to be treated or over the pads and clean pads as per 4.2 between patients to reduce chance of patient to patient cross-contamination. A transparent sterile dressing may also be used. Only use clear plastic and change between patients. Do not use anything that may block the photo energy – i.e. no socks, pantyhose or other clothing; no bandages or casts; no opaque creams or ointments.
- 4.2 Clean Therapy Pads regularly with a hospital-grade disinfectant like Sanizide Plus. Do not autoclave or immerse Therapy Pads or Control Unit in liquid of any kind as this practice will corrode the electronic circuitry and cause malfunction.
- 4.3 If used on a patient with a known MRSA, HIV or other infection, extra precautions should be taken to ensure instrument, pads, straps and wires are not contaminated before using with another patient.

## 5.0 Precautions and Remarks

- 5.1 **Do not use over or near the womb of a pregnant women or directly over an active cancerous lesion.** The effects of Anodyne Therapy with these patients are unknown.
- 5.2 **Safe to use over all implants,** pins, screws, pacemakers and defibrillators, because the system does not emit deep heat or electrical charges.
- 5.3 **Electrical Precautions**
- 5.3.1 - Use only supplied attachment straps, paper tape, gravity or clothing to hold pads in place. Do not use pins or other metallic materials to hold pads.
- 5.3.2 - Do not use in water or while wet.
- 5.4 **Calibration**
- 5.4.1 - Equipment is factory-calibrated and does not require adjustment on site. There are no field serviceable components.
- 5.5 **Blood Glucose Monitoring**
- 5.5.1 - **Check patient blood sugars regularly to avoid hypoglycemia** – especially during the first month of Anodyne Therapy. Blood sugars may be better controlled and require less insulin and/or oral medications when patients increase their activity levels during therapy.
- 5.6 **Preventing Burns**
- 5.6.1 - **Do not apply Therapy Pads with pressure** or have patients lie on top of pad(s).
- 5.6.2 - Never use for more than 45 minutes per area treated.
- 5.6.3 - Do not use over a topical heating agent like BenGay or Icy Hot.
- 5.6.4 - **Never treat areas with wounds or dry, thin, cracked or necrotic skin for more than 30 minutes or at an energy setting more than 8 bars.**

## 5.0 Precautions and Remarks - *Continued*

- 5.6.5 - Check patients every 10 minutes
- 5.6.6 - Never allow patients to sleep with Therapy Pads turned on.
- 5.6.7 - Be especially careful when treating bony areas - i.e. ankles, back of knee, shins.
- 5.6.8 - ***Do not treat top of feet or hands.***
- 5.6.9 - Always turn the system off between patient treatments.

## 6.0 General Procedure

### 6.1 Equipment Set Up

- 6.1.1 - Plug power cord into transformer and other end into an electrical outlet and turn on with on-off switch on top of unit. Green light on transformer should illuminate.
- 6.1.2 - Plug the ends of the cords of all the Therapy Pads into the therapy pad connectors on the Control Unit. Be sure they are inserted firmly into the connectors.
- 6.1.3 - Turn Energy Control dial all the way to the right. The Energy Control Indicators should show 10 red bars on both sides of the unit. If they do not, wait a few minutes for unit to warm up. (Note: If only 1 cord is plugged into a single connector on each side, the Energy Control Indicators will register 5-6 bars.)
- 6.1.4 - If using an 8 pad system (see bottom of unit), *always use with 2 pads per connector.*

### 6.2 Doing a Treatment – Overall Guidelines

- 6.2.1 - Cover pads or patient's skin with a clear plastic barrier as indicated in section 4.1.
- 6.2.2 - *Lightly* place pad(s) on area to be treated ensuring as many diodes as possible are in direct contact with the skin. Attach with Velcro strap, paper tape or elastic bandage or hold in place with clothing or gravity. Do not use metal pins.
- 6.2.3 - Determine appropriate Energy Level (5-10 red bars) for patient's condition and treat for appropriate length of time per guidelines in Section 7.0. If pads are removed from one connector per side, energy setting should never display more than 5-6 bars. *If using only one connector per side, the bars should be adjusted to half of the protocol setting (eg. 10 bars—set at 5).*
- 6.2.4 - Determine the appropriate treatment time and frequency based on the patient's condition. See section 7.0 for guidelines.
- 6.2.5 - Turn off Control Unit between patients to allow pads to return to room temperature.

## 7.0 Clinical Treatment Protocol Guidelines

*Note that these are only guidelines and may need to be adjusted or changed with individual patients or as treatment progresses.*

### 7.1 Pain or Decreased Circulation in the Extremities

#### 7.1.1 - Pad Placement

- 4 pads per extremity - 2 pads on each side of calf and 2 pads on bottom of feet forming a "T" shape (one therapy pad lengthwise along the arch of the foot, and one therapy pad across the ball of the foot)).
- Start treatments proximally on leg where evidence of decreased circulation/pain begins and move distally toward feet as pain/circulation impairment improves.
- If patient has edema, place one or two pads directly over the edematous area, one pad at the line where the edema begins and one pad above the edema to increase blood flow out of the area.
- May treat bottom of hands or wrists as well.

**7.1.2 - Energy Level** – 6-8 bars (Lower end of scale if poor skin integrity/wounds or very thin skin – as in patients on long term prednisone therapy)

**7.1.3 - Time of Treatment** – 30-45 minutes

**7.1.4 - Frequency** - Minimum of 3 times per week for 4 weeks; some patients may require more frequent treatments. Frequency may need to be lowered in certain situations, especially later in the care plan. However, therapy failure may occur if treatments are less than 3 times per week in some patients. After therapy is complete, patients should use daily at home for 90 days and then gradually reduce to 1-3 times per week to maintain increased circulation and continue exercise program

## **7.0 Clinical Treatment Protocol Guidelines - Continued**

### **7.2 Other painful and/or circulatory conditions**

#### **7.2.1 - Pad Placement**

- 2 pads directly over area to be treated (or at the source of the pain in the case of referred pain) with clear plastic barrier between skin and therapy pad.
- If too painful, pads may be placed on each side of treatment area until patient can tolerate direct contact with pads.
- Additional pads may also be placed proximal to the treatment area to increase blood flow into the area.

**7.2.2 - Energy Level** – 6-10 bars depending on skin integrity

**7.2.3 - Time of Treatment** – 20-45 minutes

**7.2.4 - Frequency** – Daily if possible, but at least 3 times per week. May be used as needed for pain up to 3 times per day (separate treatments by 4 hours)

## **8.0 Normal Patient Physiological Changes**

### **8.1 Neural**

**8.1.1** - Patient may regain sensation as circulation increases.

**8.1.2** - It is normal for patient to experience warmth during treatment. If patient reports pads are too warm for comfort, turn down Energy Dial and/or reduce therapy time.

**8.1.3** - Patient may experience temporary tingling or pain as circulation returns to area. This will usually resolve in most cases within 3-6 treatments. If this occurs and is very uncomfortable: a) Lower energy level; b) Shorten treatment times; c) Try more frequent shorter treatments; d) Try moving Therapy Pads further up on limb to improve venous evacuation e) Try reducing number of pads per limb to 3 or even 2 if necessary for a few treatments.

**8.2 Blood Glucose** - When increasing activity levels, check blood sugars frequently and adjust medications as appropriate.

### **8.3 Skin, Hair, Nails**

**8.3.1** - Treated area may be pink after treatment due to vasodilation. This should return to normal within a few hours.

**8.3.2** - Toenails and pedal hair may grow.

**8.3.3** - Skin may perspire more in area treated – especially patients with edema.

**8.3.4** - Dry or necrotic skin may peel or flake off allowing new skin to break through.

## **9.0 Equipment Care, Maintenance, Troubleshooting, Vendor Information**

### **9.1 Handle Control Unit with care.**

**9.1.1** - Do not unplug from wall by pulling power cord. When unplugging the Therapy Pads from the Control Unit, twist clockwise while pulling gently to reduce stress on connectors.

**9.1.2** - Do not wrap cords around Therapy Pads. Instead, store cords by gently folding them in a figure 8 configuration and holding them with the Velcro straps.

**9.1.3** - Never carry Therapy Pads or Control Unit by cords.

### **9.2 Handle Therapy Pads with care.**

**9.2.1** - When removing Velcro straps, pull gently to avoid pulling Therapy Pads apart.

**9.2.2** - Keep pads clean by covering treatment area or pad with clear plastic barrier.

**9.2.3** - Disinfect pad surface with hospital-grade disinfectant like a 1:10 bleach solution. Spray lightly and wipe with clean cloth. Do not immerse, soak or saturate. Do not autoclave.

### **9.3 Troubleshooting – Call 1-800-521-6664 for assistance 8 AM – 5 PM EST**

#### **9.3.1 Bars do not go to 10 bars when turned on, flicker or do not stay at level set**

- Ensure pads are plugged firmly into Control Unit connectors.
- Ensure electrical cord is plugged firmly into Control Unit and into wall outlet.
- Check another electrical outlet to see if problem still present.
- Remove extension cord (if used) and try again.
- Allow unit to warm up if cool.
- Older units only: Check fuse on back and replace with 5 amp slow-blow fuse.

## **9.0 Equipment Care, Maintenance, Troubleshooting - *Continued***

### **9.3.2 Patient not responding as expected**

- Wearing socks, clothing, bandage, opaque cream or other barrier to light.
- Frequency of therapy inadequate for condition.
- Duration of condition - Long-standing conditions may take longer to resolve or require more photo energy. Try adding a few extra pads to protocol if you have a second unit.
- In conditions with evidence of poor circulation, try treating further proximally to ensure adequate circulation to the area..
- Underlying cause of condition is not at treatment site. (eg. referred pain extremities from spinal compression)
- Surgeries – Existing scar tissue can cause condition to take longer to resolve.
- Condition does not respond to known effects of increased circulation.
- Nutrition for healing is deficient (L-arginine, magnesium, oxygen, folic acid)

### **9.3.3 Pads separating to expose electronics**

- Call toll-free number to have pads repaired or replaced.

### **9.3.4 Unit or pads get too warm**

- Verify that bars go no higher than 6 bars *with pads only plugged into one connector per side.*
- Turn system off between patients.
- Remember that some patients may become hypersensitive as blood flow returns and may perceive warmth as heat.

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