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Anodyne[®] Therapy Professional System

Model 480



Important Safety Information and Instructions

Read Entire Booklet Before Operating



TABLE OF CONTENTS

Contraindications.....	3
Adverse Reactions.....	3
Warnings and Precautions	3-4
Instructions for Use.....	5-10
Infection Control	11
Care and Maintenance	11
Warranty	11
Product Troubleshooting.....	12
Declarations	13-14

NOTES

The Anodyne® Therapy System is a noninvasive, drug-free medical device that delivers Monochromatic Infrared Energy (MIRE™) through infrared light-emitting diodes, with a wavelength of 890 nm, that are mounted in flexible therapy pads. The FDA has cleared this device for use in the United States with indicated uses for temporarily increasing local circulation and reducing pain, stiffness and muscle spasm.

Please review this manual in its entirety prior to using this system. If you have any questions, comments or concerns, please call Anodyne Therapy, LLC at 800-521-6664 or visit www.anodynetherapy.com.





DECLARATION - ELECTROMAGNETIC EMISSIONS

The Anodyne® Therapy System, Model 480, is intended for use in the electromagnetic environment specified below. The user of the Model 480 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions	Group 1	The Model 480 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supply buildings used for domestic purposes.
RF emissions	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/Flicker emissions IEC 61000-3-3	Complies	

DECLARATION - PHOTO BIOLOGICAL EMISSIONS

Each Therapy Pad contains 60 - 890 nm light emitting diodes (LEDs) that emit infrared energy at a maximum radiant intensity of 19.7 mW/sr. Based upon the supplier's LED specifications, the photo biological emissions from the Anodyne Therapy System Model 480 meet the eye safety guidelines of the IEC60825-1- Class 1, IEC62471-Exempt, and the EU Directive 2006/25/EC.



CONTRAINDICATIONS

Anodyne® Therapy should not be used directly over or near the womb during **pregnancy** or directly over **an active cancer**. The effects of this device with these types of conditions are unknown.

ADVERSE REACTIONS

- Some patients with extremely poor circulation may experience some discomfort or hypersensitivity initially. This usually resolves with 3-6 treatments.
- Potential for superficial burns.
- Potential for hypoglycemia due to increased patient activity.

WARNINGS AND PRECAUTIONS

WARNING: Use carefully. May cause serious burns. Do not use over sensitive areas or in the presence of poor circulation. The unattended use of the Model 480 by children or incapacitated persons may be dangerous.

To minimize the risks of burns, please read and follow these important precautions

Treatment Time	<ul style="list-style-type: none"> • Never treat a patient for more than 45 minutes per treated area. • If the patient's skin is very dry, thin, necrotic or sensitive, treat for the minimum times listed in the <i>Instructions for Use</i>. • Check the treatment area every 10 minutes for burns. • If there is evidence of a burn, discontinue treatment and call Anodyne Therapy at 1-800-521-6664 to report the incident. • It is recommended to utilize a timer when administering treatments as this will help to prevent over treatment
Therapy Pad Placement	<ul style="list-style-type: none"> • Use caution when treating over bony areas such as ankles, knees, elbows shins and tops of feet and hands. These areas have less tissue and are more susceptible to burns.
Therapy Pad Pressure	<ul style="list-style-type: none"> • Do not have a patient lie on top of or put pressure on the Therapy Pads during treatment. • Place pads lightly on the skin. Excessive pressure may cause burning.
Therapy Pad Warmth	<ul style="list-style-type: none"> • It is normal for patients to experience warmth during treatment. If a patient feels that the therapy is too hot for comfort, discontinue treatment and reference Device Troubleshooting on page 13 of this manual. • If you feel that your system is too hot, discontinue use and call Anodyne Therapy at 1-800-521-6664.
Skin Color Changes	<ul style="list-style-type: none"> • It is normal for the treated area to be slightly pink after treatment. This is a sign of increased circulation in the area and should go away within a few hours. If area is red and redness persists, stop treatment. Then reduce therapy time or decrease the energy dial setting in subsequent treatments thereafter.
Energy Setting	<ul style="list-style-type: none"> • 6-8 bars when treating patients with compromised skin integrity, circulatory compromise, insensate areas; or an open wound in the treatment area. • 8-10 bars for patients with good skin integrity.
Topical Heating Agents	<ul style="list-style-type: none"> • Do not use Therapy Pads over pain patches, or residual of; or over topical heating lotions or gels.
Other	<ul style="list-style-type: none"> • Do not saturate, soak, or immerse components in water or liquid.





WARNINGS AND PRECAUTIONS

NORMAL ENVIRONMENTAL CONDITIONS

- An ambient temperature range of +10 degrees C to +40 degrees C (50° F to 104° F).
- A relative humidity range of 30% to 75%.
- An atmospheric pressure range of 500 hPa to 1060 hPa.

ENVIRONMENTAL CONDITIONS FOR TRANSPORTATION AND STORAGE

- An ambient temperature range of -40 degrees C to 70 degrees C (-40° F to 158° F).
- A relative humidity range of 10 to 100RH including condensation. Be sure not to store in excessively damp location.
- An atmospheric pressure range of 500 hPa to 1060 hPa.
- Device is packaged to maintain cleanliness and minimize egress of water.

CAUTION: THIS IS AN ELECTRICAL DEVICE AND CAN CAUSE ELECTRICAL SHOCK.

Electrical Precautions

- To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
- This equipment is intended for use with Anodyne® Therapy pad cables only.
- The Anodyne® Therapy System needs to be installed and put into service according to the information supplied with this Instruction Manual.
- No modification of this equipment is allowed.
- Use only the supplied attachment straps, paper tape, gravity or applicators approved in this manual to maintain the Therapy pad position. Do not use pins or other metallic materials as a means of attachment.
- Do not use a portable electric generator as a power source.
- The Anodyne® Therapy System is an electronic device in which a portion of the electronics may be hazardous. As such, the device should be disposed of in an environmentally responsible manner. The device should be disposed of in a hazardous waste management facility in your local area at the end of its useful life.
- **Avoid using this system in water, near water or while the device or user is wet. This may cause burn or electrical shock.**

Markings and Symbols

	Consult Accompanying Documents	O	Off (power: disconnection from the mains)		Separate Collection for Electrical and Electronic Equipment
	Alternating Current	I	On (power: connection to the mains)		Type B Applied Part
	Direct Current		Compliant to the ISO 13485 Standard		

DECLARATION - ELECTROMAGNETIC IMMUNITY

The Anodyne® Therapy System, Model 480 is intended for use in the electromagnetic environment specified below. The user of this product should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+ - 6 kV contact + - 8 kV air	+ - 6 kV contact + - 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-5	+ - 2 kV for power supply lines + - 1 kV for i/o lines	+ - 2 kV for power supply lines + - 1 kV for i/o lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ - 1 kV differential mode + - 2 kV common mode	+ - 1 kV differential mode + - 2 kV common mode	Main power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) <5% UT (>95% dip in UT) for 5 s	<5% Ut (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) <5% UT (>95% dip in UT) for 5 s	Main power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field. ISO 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position Model 480 further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE: UT is the a.c. main voltage prior to application of the test level.



DEVICE TROUBLESHOOTING AND SERVICING

Problem	Troubleshooting
1a. All 10 Energy Bars do not illuminate	<ul style="list-style-type: none"> • Ensure Therapy Pads are plugged firmly into the jack on the Control Unit. • If you switch the Therapy Pads to the opposite jack, does the problem still occur? • Check the Therapy Pads with a digital camera - are some of the lights on the Therapy Pad illuminated while others are not? • Do the Energy Bars stay at a fixed setting of 5 or 6 or do they flicker or jump? Press on dial 'potentiometer' for visual confirmation. (If Yes, see 1b) • Manipulate the Therapy Pad wires, does this cause the Energy Bar reading to increase or decrease? • If manipulation of the Therapy Pads alone causes the bars to flicker, the problem likely exists in the Therapy Pads and not the Control Unit. • Discontinue System use and call Anodyne Therapy at 1-800-521-6664 to arrange for service.
1b. Energy Bars flicker or do not stay at level set	<ul style="list-style-type: none"> • Ensure Therapy Pads are plugged firmly into the jack on the Control Unit. • Perform the following actions - without touching the Therapy Pads: <ul style="list-style-type: none"> - Press on dial 'potentiometer' to see if flickering occurs. - Turn the dial 'potentiometer' slowly to see if flickering occurs. • If touching 'potentiometer' causes bars to flicker, the problem likely exists in the Control Unit. • Discontinue System use and call Anodyne Therapy at 1-800-521-6664 to arrange for service.
2. Therapy Pad array cords are damaged	<ul style="list-style-type: none"> • Wires exposed or Therapy Pads separating. • Discontinue System use and call Anodyne Therapy at 1-800-521-6664 to arrange for service.
3. Therapy Pads or Control Unit getting too hot	<ul style="list-style-type: none"> • A therapeutic warmth is normal, however, not a significant heat. • Turn the unit off in between patients, do not let it run continuously. • Have healthcare staff member confirm heat, as patient may be heat sensitive. • If problem persists, discontinue System use and call Anodyne Therapy at 1-800-521-6664 to arrange for service.

RETURNING A UNIT FOR REPAIR

To send a unit to Anodyne Therapy, LLC for repair, you must first call 1-800-521-6664 and obtain a return authorization (RA). The following information must be supplied to Anodyne Therapy, LLC before an RA number can be issued:

- 1) User name and address
- 2) Device serial number
- 3) A description of the problem with the unit.

Place return items in a closed plastic bag; place bagged items in a shipping box. DO NOT RETURN straps, velcro attachment tabs, soft shoes or carrying case.

INSTRUCTIONS FOR USE

Components

The Anodyne® Therapy System, Model 480 consists of the Main Control Unit, Therapy Pads, Attachment Straps, Velcro Strips and the Carrying Case.



Setting up the Anodyne® Therapy System

Step 1: Place the Main Control Unit securely on a table or cart to prevent it from falling and endangering the patient. Be sure there is an electrical outlet close to the System.

Step 2: Do not position the equipment in such a manner that it makes it difficult to operate the disconnection device when an appliance coupler or separable plug is used as an isolation means.

Step 3: Visually inspect both the power cord and the Therapy Pads to ensure that no exposed wires are present, as exposed wires may be unsafe and can cause electrical shock. If exposed wires exist, discontinue use and reference Device Troubleshooting on page 13 of this manual.

Step 4: Plug the cord into the power transformer on the back of the System and into an active electrical wall outlet. Be sure the electricity to the outlet is turned on.

Step 5: Plug the ends of the cords of the Therapy Pads into the Therapy Pad Connectors on the front of the Control Unit. Be sure they are inserted firmly into the Connectors.

Step 6: Turn on the Control Unit using the On/Off Switch on the top of the System.

Step 7: Turn the Energy Control Dials all the way to the right. The Energy Control Indicators should show 10 energy bars on each side when all Therapy Pads are properly connected. If all 10 bars do not illuminate, wait a few minutes and retry. If the bars still do not illuminate, discontinue use and reference Device Troubleshooting on page 13 of this manual.

Step 8: The System is now ready to be used with patients. Place the Therapy Pads on the area to be treated, being sure to place a clear plastic barrier between the Pads and the patient's skin. Specific treatment protocols are located on pages 9-11 of this manual.

Step 9: Always turn this System OFF between each session using the On/Off Switch.



INSTRUCTIONS FOR USE

Treatment Guidelines and Precautions

The recommendations appearing on the subsequent pages are meant only to be guidelines. Every patient is different and may have different experiences and results with Anodyne® Therapy treatment. Please address questions to these guidelines to Anodyne Therapy at 1-800-521-6664.

- Review all the *Warnings and Precautions* before using this device to prevent burns or electrical shocks.
- Prior to starting each treatment session, always ensure all 10 energy bars are lit when both Energy Dials have been turned all the way to the right.
- Prior to starting each therapy session, ensure the Energy Dials are adjusted to the appropriate setting for each patient.
- Prior to starting each therapy session, always completely remove topical heating or cooling agents and pain patches.
- Ensure that there is nothing between the Therapy Pads and the patient's skin except for a clear plastic barrier.
 - ☑ Ensure there are no socks or any other type of clothing between the Therapy Pads and the patient's skin.
 - ☑ Do not place the Therapy Pads over a bandage, dressing, or cast.
- For maximum effectiveness, ensure all of the diodes of the Therapy Pads are in light contact with the skin.
- Do not use if System materials cause skin irritation.
- This System may be safely used over metal implants, pins and screws and with people with pacemakers and defibrillators.
- This System may be used adjunctively with other therapeutic modalities.
- Always separate Anodyne® Therapy sessions by a minimum of four hours.
- Do not leave this System unattended around small children or pets.
- Do not saturate, soak or immerse components in water or liquid.

Normal Physiological Responses

- Patients may feel a therapeutic warmth during an treatment session.
- Patients with impaired circulation in the extremities, may experience tingling and pulsing as circulation returns to the area. *If this causes discomfort:*
 - Reduce treatment time
 - Increase frequency of treatments
 - Move Therapy Pads further up on legs or arms
- Patients may experience re-growth of hair or toenails as this is an indication of increased micro circulation in the legs and feet.
- Treated area may be slightly pink after a treatment session.
- As circulation increases, it is normal for lesions near the treatment area to increase amount of exudate after a treatment session.
- As circulation increases, it is normal for dry and necrotic skin near the treatment area to peel or slough off exposing new skin below.

CARE AND MAINTENANCE

The Anodyne® Therapy System is a sophisticated medical device. The following care and maintenance will extend the life of your unit:

- Be careful not to drop the System as this could damage the circuitry.
- Never pull the Therapy Pads out of the Control Unit by the cords.
- Never wrap cords around the Therapy Pads. This may cause the Therapy Pads to separate.
- Never carry the Therapy Pads or the Control Unit by the cords.
- Gently remove Velcro Straps when removing them from the Therapy Pad tops, to avoid pulling the Therapy Pads apart.
- To clean attachment straps, hand wash in cold water with a mild detergent, rinse, and air dry.
- Equipment is factory-calibrated and does not require adjustment on site. There are no field serviceable components. Contact Anodyne Therapy, LLC at 1-800-521-6664 for product servicing.

INFECTION CONTROL

- If you are treating multiple patients or treating over an open wound/lesion, always cover the Therapy Pads or the patient's skin with a clear plastic barrier.
- Always change the plastic barrier between patients to protect them from cross-contamination and discard the plastic barrier after each use.
- Keep the Therapy Pads and Control Unit clean with a hospital-grade disinfectant, as per facility protocol.
 - Spray lightly and wipe with a clean cloth only when unit is powered off.
- Do not saturate, soak, or autoclave the Therapy Pads or Control Unit when disinfecting, as per facility protocol. This may cause corrosion to the components which may increase the risk of burns or cause electrical shock.

WARRANTY

Anodyne Therapy, LLC ("Manufacturer") warrants the Anodyne® Therapy System ("The Product") to the immediate purchaser as follows:

Limited Warranty

Manufacturer warrants that The Product sold hereunder will be free from defects in material and workmanship for a period of either: two (2) years (New Systems) or one (1) year (Rebuilt Systems) from the date of purchase with normal use. If the defects are of such type and nature as to be covered by this warranty, Manufacturer shall, at its option, either repair or replace the damaged product at its expense, however consumer is responsible for any international shipping charges that may apply.

This warranty does not cover any Products that have been abused, misused, or tampered with in any way. This warranty does not cover Products damaged in natural disaster or flood; nor does it cover theft. This limited warranty is not transferable, and only applies to purchases direct from Anodyne Therapy LLC, or its authorized distributors.

THIS WARRANTY IS IN LIEU OF OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE, WHICH ARE HEREBY SPECIFICALLY DISCLAIMED.

This limited warranty gives you specific legal rights. You may have other rights, which vary from state to state. To the extent allowed by applicable law, in no event shall manufacturer be liable for any incidental, consequential, special, indirect, punitive or exemplary damages or lost profits from any breach of warranty.



INSTRUCTIONS FOR USE

Treatment of impaired circulation and or pain with an open lesion in/near the treatment area.

Therapy Pad Placement	To increase local circulation - place one or two Therapy Pads proximal to the treatment site. To reduce pain - place a minimum of two Therapy Pads directly over the affected area. <i>If tolerate direct contact is not well tolerated, place the Therapy Pads lateral, medial, proximal and distal of the affected area - until pain lessens.</i>
Energy Control Setting	5-8 bars Use lower end of range if patients: - Are hypersensitive to heat or light - Exhibit compromised skin integrity Use higher end of range if patients do not exhibit any of the above. <i>Do not treat patients with compromised skin integrity at 9 or 10 energy bars.</i>
Clinical Treatment Frequency	Daily if possible, but at least 3 times per week until symptoms resolve. May be used up to 3 times per day; separate treatments by 4 hours.
Clinical Treatment Time	20-30 minutes

Additional Treatment Notes:

- Do not treat directly over a bandage, dressing or an opaque cream - remove all non-clear dressings prior to treatment.
- As circulation increases, it is normal for lesions near the treatment area to increase amount of exudate after a session.
- As circulation increases, it is normal for dry and necrotic skin near the treatment area to peel or slough off exposing new skin below.



INSTRUCTIONS FOR USE

Treatment of impaired circulation, pain, stiffness or muscle spasm in the extremities

Therapy Pad Placement	Feet and Legs: - Place two Therapy Pads in a "T" shape on the bottom of each foot as shown below. - Place an additional Therapy Pad on the lateral and medial side of each calf where symptoms begin as shown below. - Move Therapy Pads proximal to distal as symptoms improve Hands and Arms: - Place one to two Therapy Pads on the palm of the hand - Place one to two Therapy Pads on the lateral and medial sides proximally on the arm where symptoms begin.
Energy Control Setting	6-8 bars <i>Do not treat patients with compromised skin integrity at 9 or 10 energy bars.</i>
Clinical Treatment Frequency	3 times per week for 12 treatments, or until condition improves. NOTE: Treatment with Anodyne® Therapy is not a cure for patients exhibiting impaired circulation and extremity pain due to a chronic condition. Ongoing symptomatic relief can be obtained from either periodic additional treatment in a clinical setting or through patient self-treatment with an Anodyne home system.
Clinical Treatment Time	30-40 minutes - check treated area every 10 minutes for burns.



Therapy Pads should be placed on each side of the calf and on the bottom of the foot in a "T" formation.

Additional Treatment Notes:

- Tingling and pulsing may be felt by the patient as circulation returns to the area. *If this causes discomfort:*
 - Reduce treatment time
 - Increase frequency of treatments
 - Move Therapy Pads further up legs or arms
- Tight blood glucose control for diabetics is always recommended for optimal results.
- Diabetic patients should monitor their blood glucose levels regularly due to increased activity.



INSTRUCTIONS FOR USE

Treatment of painful soft tissue injuries, muscle spasm or stiffness

Therapy Pad Placement	<p>Place a minimum of two Therapy Pads directly over the painful area (i.e., knee, elbow, neck, back, etc).</p> <p>If placement of Therapy Pads causes increased pain, place the Therapy Pads proximal, lateral and medial to the injured site.</p> <p>In patients suffering from referred pain - ensure to treat the origin of the pain.</p>
Energy Control Setting	<p>8-10 bars for patients with good skin integrity.</p> <p>6-8 bars for patients with poor skin integrity.</p> <p><i>Do not treat patients with compromised skin integrity at 9 or 10 energy bars.</i></p>
Clinical Treatment Frequency	<p>Daily if possible, but at least 3 times per week until symptoms resolve.</p> <p>May be used up to 3 times per day; separate treatments by 4 hours.</p> <p>NOTE: <i>Clinical treatment may be stopped when condition resolves. If symptoms are a result of an overuse injury biomechanical issues must also be addressed to prevent reinjury.</i></p>
Clinical Treatment Time	<p>20-45 minutes</p>

THERAPY PAD PLACEMENT EXAMPLES



The Therapy Pads can be arranged to fit any area of the body where the patient could benefit from an increase in local circulation, reduction of pain, stiffness or muscle spasm.



If there is an open wound in the treatment area, and/or if this system is being shared by more than one user;

Cover the Therapy Pads or the patient's skin with a clear plastic barrier to avoid the spread of bacteria, viruses and other microorganisms from one person to another.

