Anodyne® Therapy Consumer System

Model 120

Important Safety Information and Instructions

Read Entire Booklet Before Operating

The Anodyne® Therapy System is a noninvasive medical device that delivers Monochromatic Infrared Energy/ (MIRE™) through infrared light-emitting diodes. These diodes are mounted in flexible Therapy Pads, and emit infrared light at a wavelength of 890 nm - increasing local circulation and reducing pain, stiffness and muscle spasm where applied.

Anodyne® Therapy Systems received clearance from the US FDA in 1994 and are compliant to the ISO 13485 International Standard.

Review this manual in its entirety prior to using this system and contact Anodyne Therapy, LLC at 1-800-521-6664 with any questions, comments or concerns.

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SUMMARY

This summary is not intended to replace the complete user instructions. The entire manual should be read and understood before operating the Model 120.

Warning and Cautions

This device emits heat and may cause burns. Risk of burns is reduced in the following ways:

- Do not use for more than 30 minutes. The Model 120 has a timer that automatically turns off the unit after approximately 30 minutes.
- Never use pain patches or topical heating agents before, during, or after treatment.
- Stop treatment if the Control Unit or Therapy Pads feel too warm.
- Apply the Therapy Pads exactly as described throughout this manual.
- **Warning to decrease the risk of burns**, do not over tighten Attachment Straps, stand or put pressure on Foot Therapy. Do not treat on the top of the foot or hand and be careful treating over bony areas.

This is an electrical device. To avoid electrical shock:

- Do not use in water, near water or while wet.
- Do not use if electrical cords are frayed or you can see exposed wires.
- Do not saturate, soak or immerse components in water or liquid.
- Do not store in a wet or excessively damp location-this may cause rust or corrosion of electrical components or wiring and result in electrical shock or impair proper function of device.

SUMMARY

Basic Operating Instructions:

Components: Image of the Model 120 components are shown on page 10.

Set Up: Place the Control Unit on the floor next to you. Plug the Therapy Pad cords into the Connectors on the front of the Control Unit. Plug Power Supply into an electrical outlet. Place the Therapy Pads over the area to be treated and attach with supplied attachment straps.

If treating the foot and leg: First position two Therapy Pads into the Foot Strap. One Therapy Pad should be positioned horizontally across and under the toes, and the second Therapy Pad should be placed lengthwise and under the arch of the foot. Slide your foot into the Foot Strap and comfortably tighten to hold the Therapy Pads lightly in contact with the bottom of your foot. Place two Therapy Pads (one of each side of your calf) where your pain or discomfort begins; comfortably hold in place with the Leg Attachment Strap. (See images on pages 12-13)

Turn on Control unit to begin treatment: Push the On/Off Switch to the On position. The unit is operational if both of the green Indicator Lights on the Main Control Unit light up.

The Model 120 is designed to automatically turn off after approximate 30 minutes of use.

Treat for no longer than 30 minutes and remove.

Remove pads at the end of treatment: Loosen the attachment straps and remove the Therapy Pads from the treatment area. If you are treating the foot and leg, slide your foot out of the Foot Strap and loosen the Leg Attachment Strap to remove the Therapy Pads. Turn off the Main Control Unit, unplug from the electric outlet and store in a safe place away from children and pets.

CONTRAINDICATIONS

The Anodyne® Therapy System, Model 120 should not be used directly over or near the womb during **pregnancy** or directly over **an active cancer lesion**. The use of this device with these types of conditions are unknown.

GENERAL 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 120 by children or incapacitated persons may be dangerous.

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

Therapy Pad Placement	• Never use the Therapy Pads for more than 30 minutes in one area. • If skin is very dry, thin or sensitive, use for the minimum times listed in the *Instructions for Use*. • Slightly lift your Therapy Pads every 10 minutes to check for burns. If there is evidence of a burn, discontinue treatment and call 1-800-521-6664. • Never sleep during an active treatment session.
Therapy Pad Pressure	• Do not stand on or put excessive pressure on either of the Therapy Pads during treatment as this will increase the risk of burns**.** • Use caution when treating over bony areas such as ankles, knees, elbows, and tops of feet and hands. These areas have less tissue and are more susceptible to burns.
Therapy Pad Warmth	• It is normal to experience warmth during treatment. However, if any of the Therapy Pads feel too hot for comfort, discontinue use and call 1-800-521-6664.
Skin Color Changes	• It is normal for the treated area to be slightly pink after treatment. However, if area is red like a sunburn and stays that way for more than 8 hours - do not treat again prior to contacting 1-800-521-6664.
Topical Agents	• Do not use Therapy Pads over pain patches like Duragesic®, or residual of; or topical heating agents like BenGay® or Icy Hot®, as this may increase the likelihood of a burn.

GENERAL WARNINGS AND PRECAUTIONS

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

Electrical Precautions

- The device is intended to be connected with a medical grade power supply plugged into a standard receptacle.
- 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.
- Do not modify any portion of this equipment.
- Portable and mobile RF communications equipment can affect the proper operation of medical electronic equipment. Call 1-800-521-6664 before using this device if you, or any other member of your family, is using other medical electronic equipment in your home.
- 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.
- Like any other electrical device, do not use this system in water, near water or while wet. Use of this system in these situations could cause electrical shock.
- Do not use a portable electric generator as a power source as this may damage the electrical components of your device.
- The Anodyne® Therapy System, Model 120 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.

GENERAL WARNINGS AND PRECAUTIONS

Markings and Symbols

	Attention
O	Off (power: disconnection from the mains)
I	On (power: connection to the mains)
	Direct current
	Alternating current
	Dispose at hazardous waste facility
	Type B Applied Part
	Refer to Instruction Manual

PRECAUTIONS

- **The Model 120 has been designed for single patient use only.** Sharing this device with others may result in the spread of bacteria, viruses and other micro organisms from one person to another, and may spread disease.
- If there is an open wound present in/near the treatment area, cover the Therapy Pads or the treatment area with a clear plastic barrier to keep this system clean. Discard plastic barrier after use.
- Do not leave your Model 120 unattended around small children or pets. This could lead to serious shock, cuts and or infections.
- Discontinue use if device materials cause skin irritation.

PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

- The purpose of the Anodyne® Model 120 is for the temporary relief of pain, stiffness and muscle spasm and for temporarily increasing blood circulation.
- Instruction of Use

  The Patient is an intended Operator

- The Patient can safely use all functions of the device

COMPONENTS

The Anodyne® Therapy System, Model 120 consists of the Main Control Unit, Therapy Pads, Attachment Straps, Velcro Strips, and an optional Lower Extremity Treatment System. Also included is a carrying case, which is not pictured.

NORMAL ENVIRONMENTAL CONDITIONS

- An ambient temperature range of +20 degrees C to +25 degrees C (68° F to 77° 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.

Do not operate in a wet environment as this may cause electrical shock.

INSTRUCTIONS FOR USE

SETTING UP YOUR SYSTEM

Warning: If electrical wires are exposed, discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service. Exposed wires may be unsafe and cause electrical shock.

Step 1: Remove the device from the packaging and protective plastic bag. The plastic bag may be discarded or retained for product storage between uses.

Step 2: Read the entire user manual before using this device.

Step 3: If you are treating your feet and legs, remove socks or other hosiery - this will ensure you obtain the best results.

Step 4: Place the Control Unit on the floor or on a table next to either an easy chair or couch where you will treat yourself. Do not position the device where it could fall and cause injury. This device is portable and does not have to be set up in the same location each time.

Step 5: Plug the Power Supply into an active electrical outlet.

Step 6: Turn on the Control Unit by depressing the On/Off Switch to the On position. The Green Indicator Light will turn on (if not, please see Troubleshooting).

Step 7: The system is now ready for use. Information on pad placement and treatment times is found in the Instructions for Use on pages 14 and 15 of this user manual.

Step 8: Ending Your Treatment Session: The device will automatically turn off after 30 minutes of use. After your treatment is completed, turn the On/Off switch to the OFF position, unplug the Power Supply from the wall, and store in a safe, dry and cool place away from children and pets until the next use.

INSTRUCTIONS FOR USE

SETTING UP YOUR FOOT STRAP

Never stand or walk in the Foot Strap as this may increase your risk for a burn.

The Foot Strap is not meant to be used with multiple patients. Do not share your Foot Strap with others.

Step 1: Place oneTherapy Pad horizontally under and across the toes and the second Therapy Pad lengthwise under the arch of your foot.

Step 2: Slide the front of your foot (do not wear socks or hosiery) under the front of the Foot Strap.

Step 3: Comfortably tighten the straps over your forefoot to hold the Therapy Pads in direct contact with the bottom of your foot.

Step 4: Sit comfortably in a chair or couch with your feet on the floor to make sure that the Therapy Pads remain in contact with the bottom of your foot to maximize treatment results. **DO NOT STAND OR WALK ON THE FOOT STRAP.**

Step 5: Turn on your Model 120 by depressing the ON/OFF switch and begin your treatment following the times listed in the Instructions for Use on pages 14 and 15 of this guide. The device will automatically turn off after 30 minutes of use.

INSTRUCTIONS FOR USE

SETTING UP YOUR LEG ATTACHMENT STRAP

The Leg Attachment Strap is used to hold the Therapy Pads on the sides of your calf.

Step 1: Velcro the Therapy Pads to the Leg Attachment Strap. To ensure effective treatment, the Therapy Pads should be placed on each side of the calf, wherever the pain or discomfort begins (as demonstrated in the picture to the right). Avoid bony areas like the shin and ankle. You may need to adjust the location of the Therapy Pads on the Leg Attachment Strap to fit your leg.

Step 2: Secure the attachment strap around your leg. Be sure not to apply the strap too tightly as this will increase your risk for a burn.

ENDING YOUR TREATMENT SESSION

Step 1: The device will automatically turn off after 30 minutes of use (green indicator lights will go off). Turn the on/off switch at the back of the control unit to the OFF position. Unplug the Power Supply from the wall outlet.

Step 2: Remove the Foot Strap by sliding your foot out of the Foot Strap.

Step 3: Remove the Leg Attachment Strap by loosening the Velcro attachment.

Step 4: Store the Anodyne Model 120 in a safe, dry and cool place away from children and pets until the next use.

TREATMENT GUIDELINES

- Be sure you review all the ***Warnings and Precautions*** before using this system to prevent burns or electrical shocks.
- You may treat an area up to three times per day, separated by at least four hours between treatments.
- Treated area may be pink after therapy session, and wounds in or near the treatment area may have increased fluid discharge.
- It is normal to experience tingling and pulsing as circulation returns to the leg and foot. If the treatment becomes uncomfortable, discontinue use and call 1-800-521-6664 for assistance.
- Ensure that there is nothing (for example: sock, clothing or bandage) between the Therapy Pads and your skin except for a clear plastic barrier.
- All of the diodes should be in light, direct contact with the skin.
- This system may be safely used over metal implants, pins and screws and in people with pacemakers and defibrillators.
- It is normal to feel warmth during a therapy session. If any of the Therapy Pads feel too hot or uncomfortable, discontinue use and call 1-800-521-6664 for assistance.

Always follow your doctor's recommendations.

TREATMENT GUIDELINES

To temporarily increase circulation, decrease pain or muscle spasm in the extremities

<table>
<tr>
<td>Therapy Pad Placement</td>
<td>Feet and Legs:
- Place two Therapy Pads in the form of a “T” inside the Foot Strap.
- Place one pad on each side of calf approximately where symptoms begin using the Leg Attachment Strap.
Arms and Hands:
- Place one to two Therapy Pads on the palm of the hand.
- Place one pad on each side of the forearm or approximately where symptoms begin.
Do not apply the Therapy Pads with excessive pressure</td>
<td rowspan="4">
Pads should be placed inside the Soft Shoe like a “T” and placed on each side of the calf.

Do not place Therapy Pads on top of foot or stand on Foot Strap</td>
</tr>
<tr>
<td>Initial Usage Frequency
(First 90 days)</td>
<td>Daily for three months or until condition resolves per a physician.
Using the system less than three times per week may reduce results.</td>
</tr>
<tr>
<td>Maintenance Frequency
(Post 90 days)</td>
<td>1-3 times per week after initial 90-day period.</td>
</tr>
<tr>
<td>Treatment Time</td>
<td>30 minutes</td>
</tr>
</table>

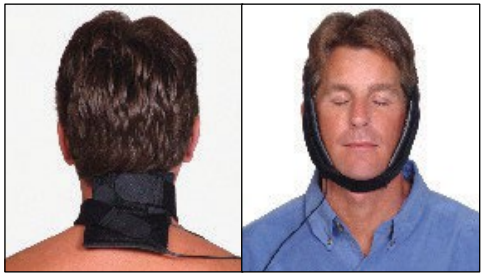
TREATMENT GUIDELINES

To temporarily relieve pain, muscle spasm or stiffness

Therapy Pad Placement	Place a minimum of two Therapy Pads directly over the painful area (i.e., knee, elbow, neck, back, etc.) If placement of Therapy Pads causes increased pain, place pads right next (lateral) to the injured site. *Do not apply the Therapy Pads with excessive pressure*
Initial Usage Frequency	Daily if possible. Minimum of three times per week.
Maintenance Usage Frequency	*Acute:* treatment may be ceased when condition resolves. *Chronic:* as needed for pain relief and circulatory maintenance.
Treatment Time	30 minutes

Therapy Pads may be easily removed from the Foot Strap for treatment of another area of the body where needed. For Therapy Pad placement examples, reference page 17 of this user manual.

PAD PLACEMENT EXAMPLES



The Therapy Pads can be arranged to fit any area of the body where the user is experiencing pain or would benefit from increased circulation.

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

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

CLEANING INSTRUCTIONS

Attachment Straps:

1. Cleaning is necessary only if the Attachment Straps become excessively soiled.
2. Remove the Attachment Straps from the Therapy Pads by placing one hand on the Strap near the Velcro and gently pulling the Therapy Pad away from the strap. Note the positioning of the Attachment Straps to the Therapy Pads so you can correctly re-attach them after cleaning.
3. Hand wash the Attachment Straps in cold water and mild detergent, rinse and air dry.
4. Re-attach the Attachment Straps to the Therapy Pads by pressing the Velcro on the Attachment Straps to the Therapy Pads.

Therapy Pads

1. Cleaning is necessary only if the Therapy Pads become excessively soiled.
2. Unplug the Model 120 from the electrical outlet.
3. Lightly spray a clean cloth with a common household disinfectant spray and wipe the cloth over the entire surface of the Therapy Pads.

Foot Strap

1. Cleaning is necessary only if the Foot Strap becomes excessively soiled.
2. Remove the Therapy Pads from the Foot Strap.
3. Engage the Velcro straps of the Foot Strap.
4. Hand wash in cold or warm water with a mild detergent, rinse and air dry.
5. Take care to keep the Velcro areas free from lint.
6. Re-attach the Therapy Pads to the Foot Strap as shown on page 12 of this user manual.

Do not saturate or soak the Therapy Pads in a cleaning or disinfection solution. This may cause corrosion to the Therapy Pads, which may increase the risk of burns.

MAINTENANCE

No special maintenance procedures are required, however, proper care of the Model 120 using the following guidelines will extend the useful life of this product.

1. **Be careful not to drop your Control Unit on a hard surface**, step on it or drop a heavy object on it - as this could damage the internal circuitry.
2. **Do not remove** the system Power Supply from an electrical outlet by pulling the cords - but rather by pulling by the electrical plug.
3. **Do not remove** the system Power Supply from the back of the Control Unit, as these components are soldered together.
4. **Do not** wrap cords around the Therapy Pads, Control unit or Power Supply. This may cause the Therapy Pads to separate or cause the cords to fray.
5. **Do not** carry or pull the system by Therapy Pads or electrical cords. Doing so may cause components to separate and or fray.
6. The device will automatically turn off after 30 minutes of use. When your treatment session is complete, **always turn your system off** using the On/Off Switch on the back of the Control Unit and unplug the Power Supply from the electric outlet.

STORAGE

When not in use, store your Model 120 in a cool, dry area away from access by either children or pets. Storage in a wet or excessively damp location may cause corrosion of electrical components or wiring that may result in electrical shock or impair the proper function of the device.

Otherwise, no special requirements exist for the transport and storage of the device. The device is shipped in a poly bag as a precaution from water damage, but this is not a requirement to transport the device.

TROUBLESHOOTING GUIDE

Problem	Troubleshooting
Only one green light illuminates on front of the Control Unit	• Slightly bend the wire that attaches the Therapy Pad to the Main Control Unit. Does this resolve the problem? • Push and turn the connectors that attach into the Main Control Unit to make sure there is a tight connection. Does this resolve the problem? • **Discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service.**
Green light on Power Supply does not illuminate/no power	• Make sure that the Power Supply plug is securely inserted into an electric outlet. • Remove any extension cords in use, and plug the system directly into the electrical outlet of the wall. • **Discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service.**
Therapy Pads are damaged	• Wires exposed or Therapy Pad materials are separating. • **Discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service.**
Control Unit or Therapy Pads get too hot	• A therapeutic warmth is normal, however, this should not cause discomfort. • Have a friend or family member confirm heat. • **If problem persists, discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service.**

DECLARATION - ELECTROMAGNETIC EMISSIONS

The Anodyne® Therapy System, Model 120, 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.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions	Group 1	The Model 120 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	The Model 120 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.
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 - 890nm light emitting diodes (LEDs) that emit infrared energy at a radiant intensity of 24.8 mW/sr. Based upon the supplier's LED specifications, the photo biological emissions from the Anodyne Therapy System Model 120 meet the eye safety guidelines of the IEC60825-1- Class 1, IEC62471- Exempt, and the EU Directive 2006/25/EC.

DECLARATION - ELECTROMAGNETIC IMMUNITY

The Anodyne® Therapy System, Model 120, 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	0.3 A/m	If image distortion occurs, it may be necessary to position Model 120 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.			

LIMITED WARRANTY

Anodyne Therapy, LLC ("Manufacturer") warrants the Anodyne®Model 120 ("The Product") to the **immediate purchaser only** 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: one (1) year 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, (minus customer shipment fees of products to manufacturer). 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 a 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.

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, Foot Straps or carrying case.

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Anodyne® Therapy
The Trusted Name in Light Therapy

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