Anodyne®

# FREEDOM 300

## Important Safety Information and Instructions

Read Entire Booklet Before Operating

Dear Valued Customer:

Thank you for choosing the Anodyne Freedom 300 for treating your foot/lower leg pain.

Using our Freedom 300 could not be any easier. Simply place the Calf Therapy Pad over your calf and the Foot Therapy Pad under your foot and then hold in place with Anodyne attachment system. Next turn on the system and receive 30 minutes of hands-free soothing relief. That's it!

**Read this entire manual before using the Freedom 300.** This will maximize your satisfaction and your safety!

All of us at Anodyne look forward to helping you feel better. Please call our Customer Service Department at 1-800-521-6664 if you ever have a question about your Freedom 300.

Sincerely,

Craig Turtzo

Craig Turtzo
President and CEO
Anodyne Therapy, LLC

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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 Freedom 300.**

**Warnings and Cautions**

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

- Never use pain patches like Duragesic® or topical heating agents like BenGay® or Icy Hot® before, during, or after treatment.
- Stop treatment if the Treatment Pads feel too warm for comfort.
- Apply the Treatment Pads exactly as described throughout this manual. Do not overtighten attachment straps or stand on Foot Treatment Pad as the LED surfaces may reach a max temperature of 127°F.
- Do not use if you have a sensitivity to silver metal.

**This is an electrical device. To avoid electrical shock:**

- Do not use this system in water, near water or while wet.
- Do not use this system if electrical cords are frayed or you can see exposed wires.
- Do not saturate, soak or immerse system or components in water or liquid.
- Do not store this system in a wet or excessively damp location as this may cause rust or corrosion of electrical components or wiring. Damage to the electrical components could result in electrical shock or could result in the device not functioning properly.

# SUMMARY

**Basic Operating Instructions**

**Set Up:** Plug Power Supply into an electrical outlet and depress the On/Off Switch on the Control Unit to the On position. If the Green Indicator Light turns on the device is operational. Turn the On/Off Switch to the Off position.

**Put the Calf Treatment Pad over the back of your calf:** Loosen the top and bottom Attachment Straps; slide over your foot onto your bare calf (do not use socks or stockings); and tighten the Attachment Straps and press Velcro ends to hold in place.

**Put the Foot Treatment Pad on the bottom of your foot:** Loosen the front attachment straps of the Sandal so you can slide your foot easily into the Sandal. Slide your bare forefoot (do not wear socks or stockings) into the sandal, tighten to hold in place on your foot. The back of your heel should be positioned at the rounded side of the Foot Treatment Pad.

⚠ ***Warning: Do not over tighten Attachment Straps or stand on Foot Treatment Pad as this may increase risk of burns.***

**Turn on Control unit to begin treatment:** Depress the On/Off switch on the Control Unit to begin treatment (note: the green indicator light will turn green for 30 minutes. The unit will automatically turn off after 30 minutes of operation. Remove at the end of the 30 minutes (when the unit turns off).

⚠ ***Warning: Immediately remove Treatment Pads if they feel too warm for comfort as you may be at an increased risk for burn.***

**Remove Treatment Pads at the end of treatment:** Loosen Attachment Straps of the Calf and Foot Treatment Pads and slip off of the leg and foot. Turn off Control Unit, unplug from electrical outlet, and store in a safe place away from children and pets.

## CONTRAINDICATIONS

The Anodyne® Freedom 300 should not be used directly over or near the womb during pregnancy or directly over an active cancer lesion. The effects of the Freedom 300 (like other modalities) 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 Freedom 300 by children or incapacitated persons may be dangerous.**

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

| | |
|---|---|
| Treatment Pad Placement | • Only place the Treatment Pads on the back of the calf and on the bottom of the foot. Treating other areas with less circulation may increase the likelihood of a burn. |
| Treatment Pad Pressure | • Do not stand on or put excessive pressure on either of the Treatment Pads during treatment. |
| Treatment Pad Warmth | • It is normal to experience a slight warmth during treatment. If any of the Treatment Pads feel too hot for comfort, stop your treatment 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 Treatment Pads over pain patches like Duragesic®, or residual of; or topical heating agents like BenGay® or Icy Hot®. |
| Other | • Do not saturate, soak, or immerse components in water or liquid.<br>• Do not use the Freedom 300 if you have a sensitivity to silver metal.<br>• Make sure your feet and legs are thoroughly dry before use. |

# GENERAL WARNINGS AND PRECAUTIONS

**CAUTION: This is an electrical device and can cause electrical shock.**

### Electrical Precautions

- The Control Unit is powered by a certified external transformer, part number SM36DU09GSTR, input rated 100V to 240V AC, 50 - 60 Hz, 1.0A, output rated 9V DC, 3.0A max. The device is intended to be plugged into a standard household electrical receptacle.

- 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.

- Like any other electrical device, do not use the Freedom 300 in water, near water or while wet. Use of the Freedom 300 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 Freedom 300.

- The Freedom 300 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.

### Markings and Symbols

| | |
|---|---|
| | Caution, consult accompanying documents |
| O | Off (power: disconnection from the mains) |
| I | On (power: connection to the mains) |
| | Alternating Current |
| | Direct Current |
| | Dispose at hazardous waste facility |
| | Applied parts type B |

# GENERAL WARNINGS AND PRECAUTIONS

## GENERAL WARNINGS

- **The Anodyne® Freedom 300 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 the treatment area**, cover the Treatment Pads or your affected foot or leg with a clear plastic barrier (clear plastic wrap or clear plastic bag) to keep the Freedom 300 clean.

- Do not leave your Freedom 300 unattended around small children or pets. This could lead to serious shock, cuts and or infections.

- Do not use if device materials cause skin irritation.

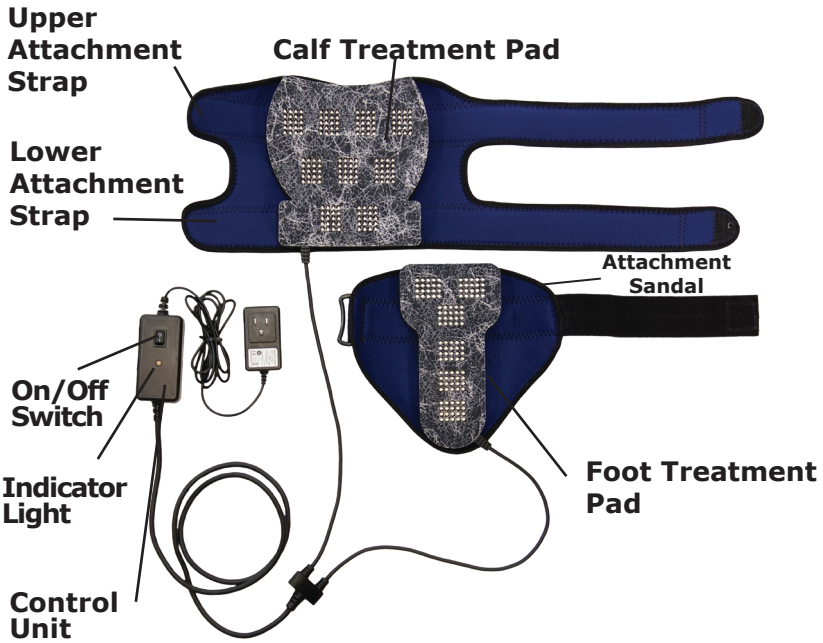
## PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

- The purpose of the Anodyne® Freedom 300 is to promote the temporary relief of pain, stiffness and muscle spasm and for temporarily increasing blood circulation to the lower leg and foot.

> **NOTE:** When the Freedom 300 is turned on (indicator light turns green), it will deliver a 30 minute treatment cycle and then automatically turn off (the indicator light will turn from green to unlit).

## COMPONENTS

The Anodyne® Freedom 300 includes a Calf Treatment Pad with Attachment Straps and a Foot Treatment Pad with an Attachment Sandal, Control Unit and Power Supply.




### Environmental Conditions Affecting Use

- Operating temperature: 0° to 40° C (0° to 104° F)
- Storage Temperature: -20° to 85° C (-4° to 185° F)
- Relative Humidity 5% to 95% Non-Condensing

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

# INSTRUCTIONS FOR USE

## SETTING UP YOUR FREEDOM 300

**Warning:** *If you can see any exposed wires in the electrical cords or their connection, discontinue use and call 1-800-521-6664. Exposed wires may be unsafe and cause electrical shock.*

- **STEP 1:** Remove the system 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 instruction manual prior to first use.
- **STEP 3:** Remove socks or other hosiery.
- **STEP 4:** Place the Control Unit on the floor or on a table next to your seat where you will receive your treatment. Be sure there is an electrical outlet close by. The Freedom 300 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.

**Note:** If you do not set up the Freedom 300 as directed, it will not function properly but there are no other adverse consequences.

# INSTRUCTIONS FOR USE

## OPERATING YOUR FREEDOM 300

**Warning:** *The Freedom 300 emits heat and may cause burns! If either the Calf Treatment Pad or Foot Treatment Pad feels too hot, immediately remove both Treatment Pads and stop treatment by depressing the On/Off switch on the Control Unit to the OFF position. Call 1-800-521-6664 prior to using again.*

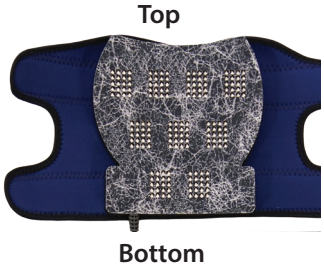
**STEP 1:** While the system is turned OFF, for your safety, visually inspect the system to make sure that none of the electrical cords are frayed and that there are no exposed wires.

**STEP 2:** Put on the Calf Treatment Pad - detailed in Steps 2a - 2g below.

**Step 2a:** Loosen the Upper and Lower Attachment Straps on Calf Treatment Pad so you can slide the Attachment Straps over your foot and onto your bare calf.

**Step 2b:** Pull the Velcro ends of the Top Attachment Straps away from the sides of the Leg Attachment Strap.

**Note:** For optimal results the side of Calf Treatment Pad with 4 diode heating clusters must be facing towards the back of the knee, while the side with 2 diode heating clusters should be facing towards the heel.



# INSTRUCTIONS FOR USE

## APPLYING THE CALF TREATMENT PAD (CONTINUED)

**Step 2c:** Pull the ends of the Top Attachment Strap until the top portion of the Leg Treatment Pad conforms comfortably to your upper calf and is in contact with your skin.

**Step 2d:** Press the Velcro ends of the Top Attachment Strap to the sides of the Leg Attachment Strap to hold in place. If you do not press the Velcro ends the Straps will loosen and your Leg Treatment Pad will not remain properly in place.

**Step 2e:** Pull the Velcro ends of the Bottom Attachment Straps away from the sides of the Leg Attachment Strap.

**Step 2f:** Pull the ends of the Bottom Attachment Strap until the bottom portion of the Leg Treatment Pad conforms comfortably to your lower calf and is in contact with your skin.

**Step 2g:** Press the Velcro end of the Bottom Strap to the sides of the Leg Attachment Strap to hold in place. If you do not press the Velcro ends the Straps will loosen and your Leg Treatment Pad will not remain properly in place.

**Note:** Be sure not to over tighten either the Calf or the Foot straps as this will cause discomfort and decrease circulation to your calf and foot.

# INSTRUCTIONS FOR USE

## APPLYING THE FOOT TREATMENT PAD

**STEP 3:** First, fasten the front attachment straps of the Sandal so you can easily slide your foot in and out of the Sandal. Next, slide your bare forefoot (do not wear socks or stockings) into the sandal. If needed, adjust the strap to hold your foot in place. The back of your heel should be positioned at the rounded side of the Foot Treatment Pad.

**Your Freedom 300 should now look like this on your calf and foot, and you are ready to begin treatment.**

**STEP 4: Start your treatment session**

**Step 4a:** ***(Starting your session)*****:** Turn the On/Off switch to the On position - the Indicator Light will turn green.

**Step 4b:** Sit on a chair or couch with your feet on the floor for **30 minutes**, until your treatment is completed.

# INSTRUCTIONS FOR USE

## STEP 5: End Your Treatment Session.

**Step 5a: Turn the On/Off switch to the Off position**.

**Step 5b:** Remove the Foot Treatment Pad by sliding your foot out of the Attachment Sandal.

**Step 5c:** Remove the Calf Treatment Pad by loosening the top and bottom Attachment Straps. Slide the Calf Treatment Pad down your leg, then over your foot.

**Step 5d:** Unplug the Power Supply from the wall outlet and store your Freedom 300 in a safe, dry and cool place away from children and pets until the next use.

**When putting on or taking off the Freedom 300:**

- **Make sure the cords and treatment straps are not tangled or caught in or under furniture**
- **Never step on or pull on the short cords that connect the foot treatment pad to the calf treatment pad.**
- **Never walk while the Freedom 300 is connected to your body.**

**Determine your choice of treatment time and frequency**

- **Treatment Time/Frequency: (1)** 30 minute treatment, daily or every other day on the symptomatic legs/feet. The system will automatically shut off after the 30 minute treatment.

**NOTE**: Depending on symptom severity - patients may use the system up to (4) 30 minute sessions per foot/leg per day. Separate treatment sessions on the same leg/foot by 3-4 hours.

# CLEANING INSTRUCTIONS

## CLEANING THE ATTACHMENT STRAPS

1. Cleaning is necessary only if the Attachment Straps become excessively soiled.
2. Unplug the Freedom 300 from the electric outlet.
3. Remove the Attachment Straps from the Treatment Pads by placing one hand on the Strap near the Velcro and gently pulling the Treatment Pad away from the strap. Note the positioning of the Attachment Straps to the Treatment Pads so you can correctly re-attach them after cleaning.
4. Hand wash the Attachment Straps in cold water and air dry.
5. Re-attach the Attachment Straps to the Treatment Pads by pressing the Velcro on the Attachment Straps to the Treatment Pads.

## CLEANING THE FOOT OR CALF TREATMENT PADS

1. Cleaning is necessary only if the Treatment Pads become excessively soiled.
2. Unplug the Freedom 300 from the electric outlet.
3. Wipe clean using a damp cloth moistured with mild detergent and water solution. Do not saturate or use bleach.

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

## MAINTENANCE

No special maintenance procedures are required, however, proper care of the Freedom 300 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 circuitry.

2. **Do not** remove the system Power Supply from an electrical outlet by pulling the cords.

3. **Do not** wrap cords around the Foot or Calf Treatment Pads, Control unit or Power Supply. This may cause the electrical cords to fray.

5. **Do not** pull the Foot Treatment Pad, Calf Treatment Pad along the floor by the cords. This may damage system components and or cause the electrical cords to fray.

6. When your therapy session is complete, **always turn your system off** using the On/Off Switch on the Control Unit and unplug the Power Supply from the electric outlet.

7. **Do not** take the Foot or Calf Treatment Pads, or Power Supply apart or remove any of the cords from their attachment to other components. Doing so may damage the system components, prevent the Freedom 300 from working properly and void product warranty.

## STORAGE

When not in use, store your Freedom 300 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 |
|---|---|
| **Green light does not turn on when you press the ON button of the Control Unit** | • Make sure that the Power Supply is securely plugged into an electric outlet If the green light is not working, try another outlet.<br>• Remove any extension cords in use, and plug the system directly into the electrical outlet of the wall.<br>• **Discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service.** |
| **Green light comes on at the start of treatment, but does not turn off after 30 minutes** | • **Discontinue system use and call Anodyne Therapy, LLC at 1-800-521-6664 to arrange for service.** |
| **Treatment Pads pulling apart from cords** | • **Discontinue system use and call Anodyne Therapy, LLC 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.**

# LIMITED WARRANTY

Anodyne Therapy, LLC ("Manufacturer") warrants the Anodyne® Freedom 300 ("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 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 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.

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