CoreControl™ powered by RTX

Rapid Thermal Exchange System

User's Manual

For Heating/Cooling Model # 200962-006B

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Caution: Thoroughly read all instructions prior to operating the device.

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Congratulations on your purchase of CoreControl™, the only scientifically proven, non-invasive core cooling and heating device.

DESCRIPTION

CoreControl™ is a hand held device that is used to rapidly deliver a thermal load to the body core of an individual. Increases or decreases in internal core body temperature can limit one's ability to do physical work and impair cognitive function, especially while exercising or working in an extreme environment. In these circumstances, maintaining optimal core temperature enhances physical and mental performance. **Core Control™** utilizes the specialized blood vessels that exist in the palms of the hand – the body's radiator – that are designed for thermal exchange. The combined application of a slight vacuum and optimal temperature enhances the natural heat exchange of these radiator structures cooling or warming a person quickly.

Core Control™ consists of a temperature controlled cone inside a vacuum chamber. The chamber is attached by tubing to a thermal source. The vacuum pump, water pump, and battery are located in the base of the unit. The battery is recharged using the battery charger included.

INTENDED USE

Cooling: CoreControl™ is designed to noninvasively cool a person's core body temperature when it has become hyperthermic (overheated). This can occur while wearing protective clothing or working in a hot environment, and/or during vigorous exercise.
Heating: CoreControl™ may also be used to warm a person's core body temperature when it is below normal. This can occur when the body has been exposed to cold temperatures for extended periods of time.

WARNING
This device **IS NOT** intended to provide adequate cooling or heating where the internal body core temperature is rising or falling uncontrollably, or is greater than 105°F (40.5°C) or lower than 90°F (32°C). In these cases, get **IMMEDIATE MEDICAL ATTENTION**!

CAUTIONS

- **CoreControl™** is designed to operate in environmental temperatures of 35°-120°F (2° - 49°C).
- Kinking of the hose can cause **CoreControl™** to cease functioning effectively.
- Tightly squeezing the cooling cone can cause **CoreControl™** to be ineffective.
- Adjusting the water temperature up or down may impact the effectiveness of the device.

Please consult AVAcore if you have questions about the set point temperature of the device.

- Use only clean water sources to reduce risk of plugging pumps.
- Store unit out of direct sunlight, in a clean, well ventilated area at room temperature.
- Do not use outdoors in the rain or snow.
- Do not allow **CoreControl™** to freeze when full of water. If freezing is a possibility, follow purge instructions to prevent water from freezing.

Using CoreControl™

Methods for using **CoreControl™** are described in **Attachment 1**. Ways to achieve maximum effectiveness with this technology differ according to the application.

INSTRUCTIONS FOR USE

I. Setting Up CoreControl™

Charge the battery: Plug one end of the battery charger into the Charging Port located at the side of the hand unit (Figure 1). Plug the other end into a properly grounded outlet.

Figure 1

Note: When recharging the battery, plug lithium-ion charger into a properly grounded 15 amp outlet or labeled AVAcore DC battery charger. Care should be taken to ensure that you have the appropriate cord and plug configuration for the country or vehicle in which **CoreControl™** is to be operated. Additional cord and plug configurations are available from AVAcore Technologies.

Recharging can take up to 3 hours. When completely charged, the LED on the charger will display a steady green light. When the battery is low, the light may display a red or orange color. **Core Control™** can be operated while attached to the charger. The battery should never be fully charged prior to extended storage period.

II. Mode of Operation

Cooling Mode:

(Prior to use, it is suggested that you follow priming instructions below to prevent cone temperature from being too low.)

If using the Water Bottle - Disconnect the tubes by depressing the bottle connectors and gently pulling the tubes off (Figure 2). Open the lid of the bottle and **fill with ice**. Add water to the ice until almost full and close the lid. Reconnect the tubes by pushing them onto the bottle connectors until a "click" is heard or felt. Gently pull on the connector to insure they are locked in place.

If using the Med Eng Water Chiller - Connect the lines to a Med Eng water chiller (Figure 3) until a "click" is heard or felt. Gently pull on the connector to insure they are locked in place.

Figure 2

OR

Figure 3 (Four person Chiller)

Note: The water in the ice bottle will maintain the proper temperature in the hand unit for a variable amount of time depending upon use and ambient temperature. Typically it will last for 1-2 hours. The ice level can be checked and replenished at any time during the operation of **CoreControl™**.

DO NOT FREEZE THE ICE BOTTLE. Circulating water is necessary for the operation of **CoreControl™**. **The device will not operate if the entire bottle is frozen**.

Heating Mode: Fill the Water Bottle with hot tap water. Do not use water over 145°F (°63C). **CAUTION: Do NOT boil** the water as an extremely hot cone could burn the hand.

III. Priming CoreControl™

If you have just received CoreControl™, or it was drained or not recently in operation, it is advantageous to purge or flush fresh water into the cone. Follow these simple steps to purge the cone:

1. Fill water bottle with lukewarm water and connect the water lines.
2. Press the Blue Button and hold.

3. Turn the Power button on.
4. Continue holding the Blue Button down for about 1 minute while pump runs. When water is seen pumping back into the bottle, priming is complete.
5. Turn the unit off at the Power button.
6. Replace the water in bottle as needed for mode of operation.

   Cooling: Add cold water and ice to the bottle.

   Heating: Add hot water to the bottle.

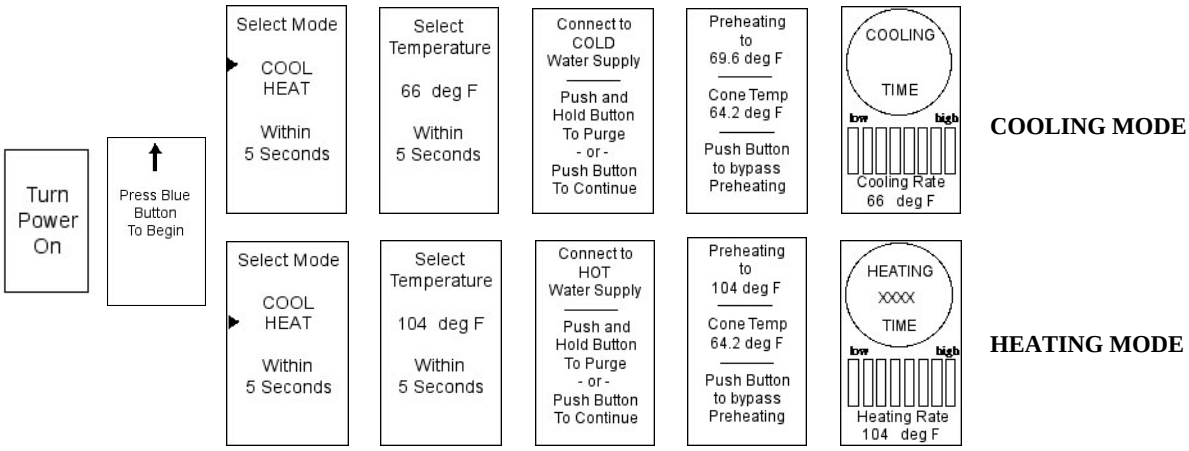
CAUTION: Purging the cone with very hot or very cold water may cause the cone temperature to be lower/higher than the desired operating set point temperature. Too low a temperature will cause vasoconstriction (reduced blood flow in the hand), significantly reducing the effectiveness of **CoreControl™** in cooling mode. A hot cone could burn the hand.

IV. Operation of CoreControl™

Turn on CoreControl™ at the power switch on the side of the hand unit (Figure 1). The display at the top of the hand unit will illuminate when **CoreControl™** is powered up. Display will provide:

- Set up of cooling or heating mode
- Operating temperature selection (Set Point)
- Operation instructions
- Timer that counts elapsed time for each cooling/heating session
- Bar graph that indicates relative thermal exchange at the hand
- Battery charging status indicator
- Vacuum system messages

Follow instructions on the displays for a quick start:



Bar Graph Display: The bars on the last display (Figure 4) measure the difference between the temperature of your hand and the cone. This feature works best on larger hands. If needed, move the hand up or down on the cone for an accurate reading.

• All bars are dark - indicates hand (and body core) temperature are significantly different than the temperature of the Cone inside of the **CoreControl™** unit.
• While cooling, dark bars disappear - indicates hand temperature is dropping, cooling in process. It is normal for the **first** bar to remain dark on an individual who is not overheated.
• While heating, dark bars disappear as the hand (and body core) heat up.
• Each bar is one degree, incremented into ten segments of 0.1°F.

V. Changing Temperature Set Points

Your Core Control™ unit will always default to a temperature setting of 66°F (19°C) in Cooling Mode and 104°F (40°C) in Heating Mode. Depending on the user, situation, climate and season of the year, higher or lower set points /operating temperatures may be desirable to improve thermal exchange between the user and **CoreControl™.**
Your **CoreControl™** device is capable of operating within a range of temperatures from 50°-77°F (10 - 25°C) in Cooling Mode and 95° and 113°F (35 - 45°C) in Heating Mode. To change the operating set point temperature, follow these simple steps.

1. Turn Power switch on.
2. Press the Blue Button to start.
3. Select the operating mode you desire (Cooling or Heating).
4. Allow the 5-second clock to count down and the next screen on the display to appear.
5. Press the Blue Button to change the temperature. Keep pressing the Blue Button until the desired set point temperature is displayed. The temperature will "wrap" around. The cooling mode set point lowers and the heating mode set point rises, with each press of the button.

Allow the 5-second clock to elapse and the next screen will appear.

VI. Using CoreControl™

1. Insert Hand: Place your hand comfortably around the aluminum cone inside the hand unit using either bare hand (Figure 5)**.**

Do not grip the cone tightly or so loosely that you lose hand contact with the cone. Holding the cone too tightly will impede the blood circulation through the hand surface. Holding the cone too loosely will reduce heat transfer. For most effective use, you should continuously maintain hand contact with the cone with the hand stationary, mid-chest level.

Display reads:

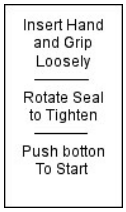


Figure 5

IMPORTANT: YOU MUST GRASP THE CONE WITH A BARE HAND. The device will not transfer heat if you grasp the cone with a gloved or taped hand. The wrist seal can be torn by bulky rings, bracelets, metal finger braces, and other sharp surfaces. Take care not to cut or damage the seal.

2. Turn Wrist Seal: Grasp the outside of the wrist seal with the other hand and turn counter-clockwise until the seal **is snug around your wrist** (Figure 6). Do not over-tighten**.** Do not allow any clothing or jewelry to come between the seal and the skin.

Figure 6

Note: Tape on the wrist **only** does not typically cause problems, but it can increase the tension number needed for the wrist seal and may impede blood flow into and out of the hand. Ensure that the tape does not stick to the seal, as it may tear upon removal.

3. Begin Operation: Press the on/off button on the top of the hand unit (Figure 7). This will activate the water and vacuum pumps. You should feel a slight vacuum being applied to your hand.

Figure 7

Note: If the wrist seal is not tightened enough, the display will give the message: **Low Vacuum: Tighten wrist seal.** *Unit will shut off in 30 seconds if the vacuum is low, displaying the countdown timer***.** If you see the Low Vacuum message, tighten the wrist seal a couple more notches, or position your arm so that it is going straight into the hand unit. Ensure that there is no clothing or jewelry between the seal and your skin. Wait five seconds to see if the error message disappears. If not, retighten a couple more notches. See troubleshooting section for more information.

CAUTION: Do not maintain a tight seal around the person's wrist or arm. A tight seal could impede blood flow, which could reduce the effectiveness of **CoreControl™.**

VII. Shutting Down CoreControl™

Ending Use: After use, press the blue button to stop the vacuum and water pump (Figure 7). To **remove your hand** from the device: **grasp the blue handle on the top of the hand unit and squeeze** so that the wrist seal returns to its zero position (Figure 8). You can also twist the outside of the wrist seal clockwise to fully return the tension to the zero position.

Display reads:

Figure 8

Note: Do not pull your hand out of the unit without releasing the tension on the wrist seal. This can cause the wrist seal to tear and leak.

Power Off: Turn off the power at the side of the hand unit when you are finished using **CoreControl™**. Disconnect the tubes from the water bottle or chiller by depressing the bottle connectors and lifting tubes off. Remove the bottle and pour out the water. If **CoreControl™** will not be used again for several hours, you may want to purge **CoreControl™** of water (see following section on Storage)

Note: To prevent mildew, ensure that the inside and outside of the water bottle is thoroughly dried, and that the insulating liner around the bottle is dried.
Do not store unit with battery fully charged. Charge battery by plugging into power supply just before needed. (Allow three hours to fully charge.)
Do not allow unit to freeze while full of water.

CLEANING

Cleaning the inside of the hand unit: Do not immerse the unit in water or any other liquid! You may wipe the inside of the hand unit with a paper towel or cotton cloth moistened with soapy water at any time.

Cleaning the outside of the hand unit: The outside of the hand unit can get wet and still operate, **but do not immerse the hand unit in water**. The outside of the hand unit, tube, and bottle bag can be cleaned with a damp cloth. Be sure that the inside of the insulating bottle bag is

allowed to dry between uses so that it does not mildew.

Note: Do not allow alcohol to come into contact with the membrane seal as this may damage the seal material.

STORAGE

After initial use and cleaning, store in a clean, well ventilated area at room temperature, about 70°F (21°C), to prevent mildew formation. IMPORTANT: **CoreControl™** should never be left in an automobile or any environment that could reach temperatures above 120°F (50°C) or below 32°F (0°C), as this could result in damage to the device.

Long Term Storage: To prevent mildew during storage, fill the water bottle with a 5% isopropyl alcohol and water mixture and "prime" the **CoreControl™** unit, as described in Section II. Be sure to connect water lines to flush unit with the water/alcohol mixture. Then, purge the unit of all water following the instructions below.

Purging CoreControl™

To "purge" the unit of all water, follow these instructions:

1. Empty bottle of all water, pull strainer basket off bottom of bottle. Lifting the strainer will cut off supply of water to unit. Replace lid.
2. Reconnect both tube fittings into bottle fittings.
3. Depress blue (on/off) button and hold down while turning power switch on (position 1). Water pump will activate after 5 seconds.
4. While continuing to hold button turn the unit upside down to allow water to drain. You will be able to watch for tubing to clear of water. Process should take about one minute. Start process again if finger slips off button.
5. When purging is complete, power the unit down.

Note: It is recommended that you **partially** discharge the battery prior to an extended storage period. Store in a cool place.

With proper care and by following the instructions in this manual, **CoreControl™** should give you many years of reliable heating and cooling. If you are experiencing trouble, please consult the troubleshooting tips below.

Accessories

To purchase accessories such as a battery charger, replacement battery, spare wrist seal cartridge, ice bottle, or extended tubing, contact AVAcore Technologies. See back page for contact information.

Troubleshooting Tips

Problem	Solution
Display reads: "Low Vacuum"  **If the Low vacuum situation remains for 30 seconds, CoreControl™ will shut down.**	Tighten the wrist seal a couple more notches, or position your arm so that it is going straight into the hand unit. Ensure that there is no clothing or jewelry between the seal and your skin. Wait five seconds to see if the error message disappears. If not, tighten a couple more notches. If you feel that the wrist seal is too tight, loosen the seal a few notches until you see the "Low Vacuum" message, and then retighten a couple of notches. Note the tension number on the top of the wrist seal. This number usually stays the same for an individual. **Note**: Check to be sure the wrist seal is not torn. Replace if necessary.
Display reads: "Low Ice" 	Check Ice water bottle and refill if necessary. If you have recently refilled the ice water bottle and or ice is visible in the bottle, continue to operate **CoreControl™** The display should return to the normal operating temperature after 30 seconds. Also, if an inadequate amount of **cold** water was being pumped into the device, this error may occur. Ensure that the tube is fully connected to the bottle and that the bottle still has ice in it. Make sure hose is not kinked. If these conditions are fulfilled, then the warning should disappear very shortly. **Note:** In very hot/sunny conditions, or when the device is first started, it is common to see this warning for about the first 30 seconds of use. In such conditions the user may want to "prime" the hand unit for 15 seconds to circulate chilled water through the hoses and cone prior to actual use. Follow the instructions priming in Section II.
Display says: "Add Hot Water" 	When using heating mode, empty and refill bottle with HOT water. **Note**: Always use caution when handling and or pouring hot water to prevent burns and or scalding.
Display says: Low Battery" 	The unit must be plugged into the charger in order to continue using it. The charger will charge the unit and provide the power necessary to continue running the unit. If the charger is not plugged in immediately, the device will automatically shut down until adequate power is provided.

Display on hand unit does not illuminate.	Be sure that the battery is fully charged and the power button is on. If ambient temperatures are above 130°F (54°C), the display may not illuminate. Place the unit in a location with a temperature less than 120°F (49°C) for several minutes.
There are bubbles in the tubes.	It is normal to have bubbles in the tubes when **CoreControl™** is first started. Most of the bubbles will disappear as you use the device.
I don't feel cooler.	It's difficult to feel **CoreControl™** extracting heat out of your body because you don't have temperature sensors deep inside your body; they are primarily on the skin surfaces. **CoreControl™** pulls heat directly out of your *core* via thermal portals in the hand, while most "cooling" technologies used today try to cool the body through the general skin surface. While using **CoreControl™** you may not "feel" cool, but you will feel more *refreshed* and be able to perform at a higher level.
I don't feel warmer.	When rewarming the body, it may take several minutes of use before the AVA's open to allow additional blood flow. This blood flow will help "carry" the heat into the core of the body.
Wrist seal is torn.	Contact AVAcore Technologies to purchase a replacement.
Device is not cooling effectively.	In special cases (in particular, some medical conditions), the water temperature set point may be inadequate to cool the user. To reprogram the default water temperature (66°F) for cooling, see instructions on temperature adjustments, Section III, or follow the instructions on the **CoreControl™** display. Make sure water bottle is filled with ice and return water is flowing into bottle. Pump may not operate unless water is flowing.
Device is not heating effectively	In some cases (in particular, some medical conditions), the water temperature set point may be inadequate to warm the user. To reprogram the default water temperature (104°F) for heating, see instructions on temperature adjustments, Section III, or follow the instructions on the **CoreControl™** display.
Water is leaking from the bottom or accumulating inside the hand piece.	Sweat or condensation collecting inside unit is normal. Stop using **CoreControl™** if water is leaking, turn off the power and contact AVAcore.

If you continue to have difficulty with the operation of **CoreControl™**, please contact AVAcore Technologies, Inc. at the contact number on the back page.

WARRANTY

AVAcore warrants to the initial purchaser ("purchaser") that each new CoreControl system ("product") purchased directly from AVAcore or an authorized AVAcore distributor will be free from defects in materials and workmanship under normal use for a period of one year from the date of its initial shipment to the purchaser (90 days for the wrist seal). Repair or replacement of products (or parts thereof) under this warranty does not extend the warranty period. Products that are not new are subject to separate warranties expressly provided in connection with the sale of such products.

The obligations of AVAcore under this warranty shall be limited to repair or replacement (at AVAcore's option) of any product (or part thereof) under warranty that AVAcore reasonably determines to be covered by this warranty and to be defective in workmanship or materials. AVAcore shall determine whether to repair or replace products and parts covered by this warranty and will endeavor to ship the repaired or replacement product within 72 hours of receipt. All products or parts replaced shall become AVAcore's property. In the course of warranty service, AVAcore may, but shall not be required to, make engineering improvements to the warranted products or parts.

If AVAcore reasonably determines that a repair or replacement is covered by the warranty, AVAcore shall bear the costs of shipping the repaired or replacement product to the purchaser, and will reimburse the purchaser for any shipping costs paid by the purchaser. Risk of loss or damage during shipment under this warranty shall be borne by the party shipping the product.

Products shipped by the purchaser under this warranty shall be suitably packaged to protect the product. If the purchaser ships a product to AVAcore in unsuitable packaging, any physical damage in the product upon receipt by AVAcore (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the purchaser.

This warranty shall be invalid if the warranted products (or parts thereof) have been subject to misuse, neglect, or accident; have been damaged by causes external to the warranted product; have been affixed to any nonstandard accessory attachment; have had the serial number removed or made illegible; or have been disassembled, modified, serviced, or reassembled by anyone other than AVAcore, unless authorized by AVAcore.

AVAcore will not be responsible for the effect on safety, reliability, and performance of the product if:
a) assembly, extensions, readjustments, modifications, or repairs are carried out by anyone other than AVAcore or persons authorized to perform repair service on AVAcore's behalf; or b) the electrical installation does not comply with the requirements of the applicable national and international standards, including requirements of the IEC; or c) the product is not used in accordance with AVAcore's instructions for use.

THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY AVACORE, IS THE SOLE AND EXCLUSIVE WARRANTY AS TO AVACORE PRODUCTS, AND EXTENDS ONLY TO THE PURCHASER AND IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. AVACORE SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE, OR LOSS OF USE OF ANY PRODUCT.

DISCLAIMER OF WARRANTIES

The AVAcore thermal regulation devices are used in extremely variable environments, ancillary equipment connections and medical conditions. The devices may fail to function for a variety of causes, including but not limited to the medical condition of the person or the failure of the device or ancillary equipment by breakage. In addition, despite the exercise of all due care in the design, component selection, manufacture and testing prior to sale, the devices can be damaged, before, during or after use by improper handling or other intervening acts. Consequentially, no warranty is made that failure or cessation of the function of the devices will not occur or that medical complications will not follow the use of the device.

Contact Information:

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Website: www.avacore.com

(Check our website for Frequently Asked Questions, updated User's Manuals, Methods for using **CoreControl™**, publications and references.)