

# CoreControl™ powered by RTX

Rapid Thermal Exchange System

## User's Guide

Cooling Model #200962-001B to -005B



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

# CoreControl™ powered by RTX

## Rapid Thermal Exchange System

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

### DESCRIPTION

**CoreControl™** is a hand held device that is used to rapidly extract heat from the body core of a heat stressed individual. Increases in internal core body temperature can limit one's ability to do physical work and impair cognitive function, especially while exercising or working in a hot environment. In these circumstances, keeping cool enhances physical and mental performance.

**CoreControl™** utilizes the specialized blood vessels that exist in the palms of the hand – the body's radiator – that are designed to dissipate heat. It enhances the natural heat exchange of these radiator structures through the combined application of a slight vacuum and optimal temperature to cool a person quickly.

**CoreControl™** consists of a temperature controlled cooling cone inside a vacuum chamber. The chamber is attached by hose to the ice bottle. The vacuum pump and battery are located in the base of the unit. The battery is recharged using the battery charger.

### INTENDED USE

**CoreControl™** is designed to noninvasively lower a person's core body temperature when it has become hyperthermic (overheated). This can occur while working in a hot environment and/or during vigorous exercise.

### WARNING

This device **IS NOT** intended to provide adequate cooling where the internal body core temperature is rising uncontrollably or is greater than 105°F (40.5°C). In these cases, get immediate medical attention.

### CAUTIONS

- **CoreControl™** is designed to operate in environmental temperatures of 50-110°F (10 - 43°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 efficacy of the device. Please consult AVAcare prior to changing the set point temperature of the device.
- When recharging the battery, plug charger into a properly grounded 15 amp outlet. Care should be taken to ensure that you have the appropriate cord and plug configuration for the country in which **CoreControl™** is to be operated. Additional cord and plug configurations are available from AVAcare Technologies.

## INSTRUCTIONS FOR USE

### Setting Up CoreControl™

- 1. Charge the battery:** Plug one end of the battery charger into the female receptacle located at the side of the hand unit. Plug the other end into a properly grounded outlet.



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 will display a red or orange color. **CoreControl™** can be operated while attached to the charger.

- 2. Fill the ice bottle:** Disconnect the tube on the ice bottle by depressing the metal tab of the bottle connector and gently pulling the tube off. Remove the ice bottle from the bag, if desired. Open the lid of the bottle and **fill at least 3/4 full with crushed or cubed ice**. Add water to the ice until **completely** filled and close the lid. Place the bottle back into the bag and reconnect the tube by pushing the tube onto the bottle connector until a “click” is heard or felt. Gently pull on the connector to insure they are locked in place.



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 2-3 hours. The ice level can be checked and replenished at any time during the operation of **CoreControl™**.

**Note:** 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.

### Using CoreControl™

Methods for using **CoreControl™** are described in **Attachment 1**. Ways to achieve maximum effectiveness with this technology differ according to the application. Steps 3 – 7 can be repeated for cooling as needed.

**3. Turn on CoreControl™** at the power switch on the side of the hand unit. The display at the top of the hand unit will illuminate when **CoreControl™** is powered up. This display provides important user information including a:

- Timer that counts elapsed time for each cooling session
- Cooling bar graph that indicates relative heat extracted from the hand
- Battery charging status indicator
- Temperature “Set Point” (defaults to preset temperature at power-up)

**Note:** The cooling bars on the display measure the difference between the temperature of your hand and the cooling 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) is hot. Maximum cooling is needed.
- 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.



**Note:** Before you place your hand inside the unit, remove all rings, watches or other jewelry that have sharp edges or rise up from the surface of the skin. This will help protect the delicate seal material from being torn.

**4. Place your hand comfortably around the cooling cone inside the hand unit** using either hand. **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.



**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.

**5. Grasp the outside of the wrist seal with the other hand and turn counter-clockwise until the seal is snug around your wrist.** Do not over-tighten. Do not

allow any clothing or jewelry to come between the seal and the skin. Tape on the wrist 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.



**Note:** The wrist seal material is strong enough for repeated use, but it can be torn by bulky rings, bracelets, metal finger braces, and other sharp surfaces. Take care not to cut or damage the seal.

**6. Press the button on the top of the hand unit.** This will activate the water and vacuum pumps. You should feel a slight vacuum being applied to your hand.



Note: If the wrist seal is not tightened enough, the display will give the message: **Low Vacuum: check cuff for leaks**. If you see this 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™**.

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



**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.

### **Shutting Down CoreControl™**

When you are finished using **CoreControl™**, turn off the power at the side of the hand unit. Disconnect the tube from the ice bottle by depressing the metal tab and lifting tube off. Immediately replace the red cap over the end of the tubes to prevent water from leaking out. Remove the bottle and pour out the ice water. If **CoreControl™** will not be used again for several hours, you may want to drain tube and hand unit.

To prevent mildew, ensure that the inside and outside of the ice bottle is thoroughly dried, and that the insulating liner around the ice bottle is dried.

Plug the unit into the battery charger to recharge for future use.

## **CLEANING**

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

1. **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 at any time. It can also be cleaned out by adding a mixture of dishwashing liquid (small amount) and water, and swirling it around the inside of the hand unit. Always thoroughly rinse out any detergent.
2. **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.

## **STORAGE**

After initial use and cleaning, store in a 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 ice bottle with a 5% alcohol and water mixture. Run the device for 5 minutes to be sure all lines have been filled with the mixture. Empty and dry the ice bottle. It is recommended that you partially discharge the battery.

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

## Troubleshooting Tips

Problem	Solution
<b>Display says “Low vacuum: Check cuff for leaks”</b>	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.
<b>Display says “Alert: Low ice, refill ice bottle”</b>	An inadequate amount of <b>cold</b> water is being pumped into the hand unit. Ensure that the tube is fully connected to the bottle and that the bottle still has ice in it. If these conditions are fulfilled, then the warning should disappear very shortly. <b>Note:</b> If you have recently refilled the ice water bottle and/or ice is visible in the bottle, continue to operate <b>CoreControl™</b> . The display should return to the normal operating temperature after 30 seconds. 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 turn on the hand unit for 15 seconds to circulate chilled water through the hoses and cone prior to actual use.
<b>Display says: Low Battery</b>	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.
<b>Display on hand unit does not illuminate.</b>	Be sure that the battery is fully charged and the power button is on.
<b>There are bubbles in the tubes.</b>	It is normal to have bubbles in the tubes when <b>CoreControl™</b> is first started. The bubbles will disappear as you use the device.
<b>I don’t feel cooler.</b>	It’s difficult to feel <b>CoreControl™</b> extracting heat out of your body because you don’t have temperature sensors deep inside your body; they are primarily on the skin surfaces. <b>CoreControl™</b> pulls heat directly out of your <i>core</i> via

	thermal portals in the hand, while most “cooling” technologies used today try to cool the body through the general skin surface. While using <b>CoreControl™</b> you may not “feel” cool, but you will feel more <i>refreshed</i> and be able to perform at a higher level.
<b>Wrist seal is torn.</b>	Contact AVAcore Technologies to purchase a replacement seal.
<b>Device is not cooling effectively.</b>	In special cases (in particular, some medical conditions), the water temperature set point may be inadequate to cool the user. To reprogram the device to adjust the preset water temperature, see section on changing temperature set point or contact AVAcore Technologies. Instructions are available on the website at <a href="http://www.avacore.com">www.avacore.com</a> .
<b>Bars on graph in display are not illuminating or Only one bar on graph illuminates</b>	This may indicate that the user is vasoconstricted and the difference between the hand temperature and cone temperature is very small. See the section on changing temperature set point below.
<b>Water is leaking from the bottom of the unit or accumulating inside the hand piece.</b>	Contact AVAcore

If you continue to have difficulty with the operation of **CoreControl™**, please contact AVAcore Technologies at 800-AVACORE/734-332-3777 between 9AM and 5PM Eastern Time, or email questions to [info@avacore.com](mailto:info@avacore.com) .

## CHANGING TEMPERATURE SET POINTS

Your **CoreControl™** unit will default to its preset temperature each time you power it up. The set point is displayed on the screen. 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 15°-28°C. To change the operating set point temperature, follow these simple steps:

1. With **CoreControl™** powered up, press and hold the blue button on top of the unit for 7 seconds.
2. When you begin to hear the water pump run or see “Purging” on the display screen, release the blue button.
3. To change the set point temperature in .5°C increments, press the blue button in succession until you reach your desired operating set point. *Note: the set point will decrease in half-degree increments until you reach 15°C. It will then go to the highest temperature 28°C and begin decreasing again in half-degree increments.*
4. Once you have selected the desired set point, wait 7 seconds and **CoreControl™** will automatically revert back to the “normal” display screen and will be ready to operate at the new set point.

## **PURGING CORECONTROL™**

If you have not operated **CoreControl™** recently, have drained the system of water, or have left the system idle in a hot environment for several minutes, it may be desirable to purge or flush fresh water into the cooling cone. Follow these simple steps to purge the cone and refill it with fresh water.

1. With **CoreControl™** powered up, press and hold the blue button. After seven seconds, if you continue to hold the blue button down, the water pump will turn on and run, continuously flushing or filling the cone with fresh water.
2. If you are flushing the system to cool the cone after it has been sitting in a hot environment, place one hand inside the device on the cone and continue to purge until the cone feels cool to your hand.
3. If you are using **CoreControl™** after storage and or the system has been drained, it is recommended that you fill the water bottle with cool or room temperature tap water for filling and flushing the cone. Follow step one above until you see water in the return line to the bottle. Then disconnect the water bottle, empty and refill with your water and ice solution. Re-connect the bottle and you are ready to operate the system.

Caution, purging the cone with an ice water slurry (contents of the ice water bottle) may cause the cone temperature to be far lower than the desirable operating set point temperature. This may cause vasoconstriction (reduced blood flow in the hand), significantly reducing the effectiveness of **CoreControl™**.

## **Accessories**

To purchase accessories such as a battery charger or ice bottle, contact AVAcore Technologies.

## **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 AVAcure, unless authorized by AVAcure.

AVAcure 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 AVAcure or persons authorized to perform repair service on AVAcure'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 AVAcure'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 AVAcure 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.

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

#### **Patents**

Licensed Patents: Pat. No. 6,656,208; Pat. No. 6,602,277; Pat. No. 6,673,099; Pat. No. 6,966,922; Pat. No. 6,974,442 and other patents pending.