

CoreControl™ powered by RTX

Rapid Thermal Exchange System

User's Guide



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

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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, especially while exercising in a hot environment. In these circumstances, keeping cool enhances physical 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 temperature to cool a person quickly.

CoreControl consists of a temperature controlled cooling cone inside a vacuum chamber. The chamber is attached by hoses to the bag that contains the water and vacuum pumps, rechargeable battery, and ice reservoir. 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 hoses can cause **CoreControl** to cease functioning effectively.
- Tightly squeezing the cooling cone can cause **CoreControl** to be ineffective.
- Do not attempt to adjust the water temperature. It is not user-serviceable.
- 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: Unzip the top of the bag to access the charging receptacle. It is located next to the power switch. Plug one end of the battery charger into the female receptacle located at the top of the bag. Plug the other end into a properly grounded outlet.



Recharging can take up to 5 hours. When completely charged, the LED on the charger will turn green. **CoreControl[®]** can be operated while attached to the charger. If the display does not illuminate after initial charging, the battery may have been disconnected for shipping. Consult the troubleshooting section of this manual.

2. Fill the ice reservoir : Disconnect tubes on the ice reservoir by simultaneously depressing the blue buttons on the side of the connectors and lifting up. Remove the ice reservoir from the bag. Open the lid of the reservoir, leaving the intake tubes inside the container, 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 reservoir back into the bag and reconnect the tubes by pushing the connectors onto the reservoir nipples until a “click” is heard or felt. Gently pull on the connectors to insure they are locked in place. Zip up the top of the bag.



Note: The water in the ice reservoir 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 several hours. The ice level can be checked and replenished at any time during the operation of **CoreControl[®]**. Turn off the unit before adding ice.

Note: **DO NOT FREEZE THE ICE RESERVOIR.** Circulating water is necessary for the operation of CoreControl[®]. The device will not operate if the entire reservoir 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 top of the bag. 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

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 lower 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.

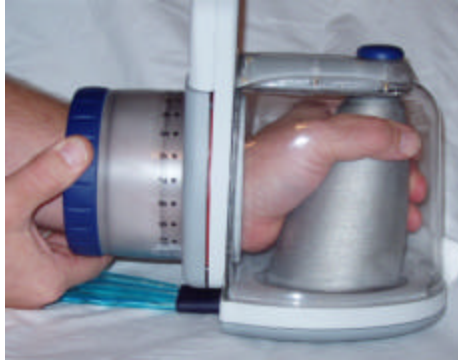
It is normal for the first bar to remain dark on an individual who is not overheated.



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.



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 top of the bag. Unzip the top of the bag. Disconnect the tubing from the ice reservoir by simultaneously pressing the two blue buttons on the sides of the connector and lifting up. Remove the ice reservoir and pour out the ice water.

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

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

CLEANING

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 and bag:** 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, hoses, and bag can be cleaned with a damp cloth. Be sure that the inside of the bag is allowed to dry between uses so that it does not mildew. The insulating liner around the ice reservoir may be removed to facilitate drying.

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 reservoir 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 reservoir.

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
<p>Display says “Low vacuum: Check cuff for leaks”</p>	<p>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.</p>
<p>Display says “Low Ice: Replace ice cartridge immediately”</p>	<p>An inadequate amount of cold water is being pumped into the hand unit. Ensure that the tubes are fully connected to the reservoir and that the reservoir still has ice in it. If these conditions are fulfilled, then the warning should disappear very shortly.</p> <p>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.</p>
<p>Display says: Low Battery</p>	<p>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. If the battery completely discharges, you will NOT initially see a red light when recharging. This is normal. After charging the light will function.</p>
<p>Display on hand unit does not illuminate.</p>	<p>Be sure that the battery is fully charged and the power button is on.</p> <p>During initial shipment of CoreControl[®], the battery may be disconnected from the charging outlet. This is done to ensure that CoreControl[®] is not inadvertently turned on during shipping. To reconnect, unzip the bag top, and remove the ice reservoir and its surrounding insulating liner from the bag (Velcro-attached). Reconnect the electrical cables that appear about half way down the bag next to the reservoir insulating liner by pushing ends together.</p>

Display on hand unit still does not illuminate.	If the battery is fully charged, the unit is turned on, and all electrical cables are attached, then the fuse may be burned out. The fuse compartment is located directly above the electrical cables identified above. Unscrew fuse holder and replace with size 1" x 1/4", 5 amp, 32 volt fuse.
There are bubbles in the tubes.	It is normal to have bubbles in the tubes when CoreControl[®] is first started. 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 <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 RTX you may not "feel" cool, but you will feel more <i>refreshed</i> and be able to perform at a higher level.
Wrist seal is torn	Contact AVAcure Technologies to purchase a replacement seal.

If you continue to have difficulty with the operation of **CoreControl[®]**, please contact AVAcure.

Accessories

To purchase accessories such as a battery charger or ice reservoir, contact AVAcure Technologies.

WARRANTY

AVAcure warrants to the initial purchaser ("purchaser") that each new CoreControl system ("product") purchased directly from AVAcure or an authorized AVAcure 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 AVAcure under this warranty shall be limited to repair or replacement (at AVAcure's option) of any product (or part thereof) under warranty that AVAcure reasonably determines to be covered by this warranty and to be defective in workmanship or materials. AVAcure 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 AVAcure's property. In the course of warranty service, AVAcure may, but shall not be required to, make engineering improvements to the warranted products or parts.

If AVAcure reasonably determines that a repair or replacement is covered by the warranty, AVAcure 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 AVAcure 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.

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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; and other patents pending.